# EXHIBIT 512

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

MDL NO. 1968

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The videotaped deposition of JAMES J. FARLEY taken by counsel for the Defendants, Actavis Totowa, LLC, Actavis, Inc., and Actavis Elizabeth, LLC, pursuant to notice and by agreement of counsel, reported by Angela S. Garrett, CSR, RPR, B-2407, at the Embassy Suites, 145 Mulberry Boulevard, Savannah, Georgia, on June 28, 2010, commencing at 9:10 a.m.

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THE VIDEOGRAPHER: Good morning. We're on record. It's 9:11 a.m. The date is June 28th, 2010. This is the videotaped deposition of James J. Farley in the matter of Digitek Product Liability Litigation, United States District Court for the Southern District of West Virginia, Charleston Division, MDL No. 1968.

This deposition is being held at Embassy Suites held at 145 Mulberry Boulevard, Savannah, Georgia, 31322. The deposition was noticed by Matthew Moriarty of Tucker, Ellis & West, LLP, from Cleveland, Ohio.

My name is Bill Kaska for McKee Court Reporting here in Savannah, Georgia. The court reporter is Angela Garrett of McKee Court Reporting, 4849 Paulsen Street, Suite 304, Savannah, Georgia, 31405-4426.

Counsel, please state your appearances for the record, please.

MR. MILLER: My name is Pete Miller of The Miller Firm for Plaintiffs.

MS. DOWNIE: Ericka Downie from Shook, Hardy & Bacon on behalf of the Mylan defendants.

MR. ANDERTON: My name is Michael Anderton with Tucker, Ellis & West on behalf of

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the Actavis defendants.
THE VIDEOGRAPHER: Thank you. Madam court reporter, would you please the witness.
JAMES J. FARLEY
having been first duly sworn testified as follows:
THE VIDEOGRAPHER: Thank you. At your leisure.
MR. ANDERTON: Thank you.
- - - - -
DIRECT EXAMINATION
BY MR. ANDERTON:
Q Good morning, Mr. Farley.
A Good morning.
Q We met a few moments ago. My name is Michael Anderton. I am with Tucker, Ellis & West in Cleveland. And I am here on behalf of the Actavis defendants in the Digitek litigation.
Will you just spell your name and provide your home address for the record, please.
A First name James, J-A-M-E-S, I usually use my middle initial, J. for Joseph, last name, Farley, F-A-R-L-E-Y. Home address is in Savannah. It's 101 Captain John's Drive, Savannah, 31410.
Q And do you have a business address as well?

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A That is my business address. I have a home business.
Q And what business do you run out of your -- do you work for out of your home?
A I do chemistry and pharmaceutical consulting.
Q Do you have a name? Is there a name for the company that you work for or operate or own?
A I call my company -- I am my company -- Cardinal Consulting and Training. And in this case I'm contracted out to do work for Smart Consulting Group in West Chester, Pennsylvania.
Q So the Cardinal Consulting and Training, do I understand correctly that you are the sole employee of that company?
A I'm everything.
Q Everything.
A That is me.
Q Okay. And you say you're contracted out by Smart Consulting in Pennsylvania?
A West Chester, Pennsylvania, suburb of Philadelphia.
Q How did that relationship come to be in existence, your current relationship with Smart Consulting in the context of this litigation?

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A I've known Nigel Smart, Dr. Nigel Smart, for over a dozen years now and we work together on projects. And most recently Nigel and his wife, Denise, formed their own business. By recently, the last half a dozen years, somewhere thereabouts.
And he will call people he knows on certain projects and contract with them and say, here's a project, would you do this aspect of the project for me. That's what I mean by contract out.
Q Okay. And is that how your relationship with -- or how your involvement in this litigation came to be? Did he contact you and ask you to be involved in some aspect of this litigation?
A Yes.
Q When did that happen?
A I'd have to check the records for initial contact, but it was around the end of last year or beginning of this year.
Q End of 2009, beginning of 2010?
A Yes.
Q After -- is it Dr. Smart?
A Dr. Nigel Smart.
Q After Dr. Smart contacted you did you ultimately come to have direct contact with counsel for the plaintiffs in this litigation?

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A Yes.
Q And how did that come to be? Did Dr. Smart put you in touch with them? Did they contact you directly? How did that happen?
A He did what is pretty much typical in situations like this. He said a gentleman named Peter Miller will be contacting you, I've given you his number and he will call you to discuss the project with you. And it was either the same day or the following day that Pete Miller did call me and we discussed the project.
Q Okay. And he said gentleman?
A I'm sorry?
Q Never mind. You're not a medical doctor, are you?
A No.
Q Your testimony a moment ago was that you provide consulting service on I think chemistry and what was the second category?
A Pharmaceuticals, general pharmaceuticals, a lot of FDA regulatory.
Q I want to find out a little bit more about that. When you say pharmaceuticals and then you expand that a little bit by saying a lot of FDA regulatory, can you give me more detail?
What does -- what type of consulting do you

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do? What do you consult in with respect to pharmaceuticals as you've described it?

A I'll go back to 1996 when I resigned my position at the FDA in Philadelphia.

Q Okay.

A And I formed Cardinal Consulting, which was just give me the name and saying I'm going to be a consultant. And initially it was analytical methods and analytical procedures because much of that was what I did.

However, in my eight years at FDA, during which time they promoted me to be director of the science branch of the Philadelphia district where 30 chemists were in my employ, I -- since I had participated in FDA inspections, since I had to assign chemists to FDA inspections and since I had to review Establishment Inspection Reports, called EIRs, and the FDA 483s and review and in some cases sign warning letters, I included that in my repertoire of services.

Q So -- I mean, you just described how you came to kind of provide consulting services and how you expanded it beyond analytical methods consulting.

Can you give me just a little more detail just about exactly what you -- what you do in a typical consulting -- or what services you will offer? I

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should -- let's start -- let's back that up.

A Uh-huh.

Q First tell me in more substance when you say you consult with respect to analytical methods or with respect to FDA regulatory, what types of activities do you actually perform?

A Uh-huh. With regard to analytical test procedures, those test procedures which are within my area of expertise, I may design it for a pharmaceutical firm or I may review one that they have and add, delete or modify as necessary or I may review one that they're having a problem with or I may visit a contract testing firm and look at their methods.

If the big firm wants to contract out they might say, Jim, go look them over and tell us that they're okay. So I could do any of those things relevant to analytical procedures. That would extend over to Good Manufacturing Practices, GMPs.

A lot of times you see it with the little c for current in front of it, but GMP is the normal term. And that would involve everything from raw material coming in to a firm, how is it tested, who tests it, what procedures, standard operating procedures, SOPs, are in place or are needed, how are -- how are these materials transported to manufacturing, what in-process

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tests are done in manufacturing, how about the qualifications of people all along the way, qualifications of training, up to and including finished goods testing, which is also called release testing because you're releasing the product to the public. So that's all the testing.

But there's more to it. You have the calibrations. You have your systems. You have the entire system, not just of the test. The test is part of the system.

It's the training of the individuals, the assignments given to the proper individuals, their experience with it. I'll pause here and look to you for -- what more do you want?

Q I think that's enough detail. You've given me a --

A Okay.

Q -- better understanding of what you do when you provide pharmaceutical consulting. And I should pause briefly, Mr. Farley, and go over a quick ground rule that I should have incorporated into the examination at the very -- you know, at the very beginning. And I apologize.

But if I ask you a question today and you don't understand it, if I say it poorly, if it just

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doesn't make sense, if for whatever reason you don't understand it, will you please ask me to say it differently or ask it differently or to rephrase it somehow?

A Yes, I will.

Q Okay. And if you answer a question that I ask you and you don't ask me to rephrase it, I will assume that you understood it as asked and that you answered it with an understanding of it as I asked it.

Is that -- is that fair?

A That's fair. I understand what you're saying now.

Q Excellent. So the consulting services that you just described in reasonably significant detail -- and I'm talking about the -- not the analytical method consulting, but the consulting services that you -- the pharmaceutical, the regulatory, how much of your current workload at Cardinal is divided between regulatory consulting and the analytical methods consulting?

A The analytical methods consulting is part of the regulatory since the methods must be designed and validated in order to be submitted to FDA. So I'm going to take my time and try to answer your question. But since regulatory includes these methods --

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Q Right.
A -- at any given time these days it could be anywhere from 10 to 40 percent. It depends on the individual project.
Q So do I understand that you would say that 60 percent or so of your current consulting work focuses on the analytical methods, purely the analytical methods review and analysis?
A No, no. That's not what I meant.
Q Okay. Then I misunderstood.
A I'll reword it.
Q Okay.
A Taking analytical methods development or review or evaluation, anything related to analytical methods as part of regulatory, that percentage of the analytical methods work that is part of my overall regulatory business can vary from 10 to 40 percent of work with time involved at any given time.
Q Okay. Okay.
A Is that --
Q All right. So you consider it all regulatory with 10 to 40 percent being the analytical methods type analysis?
A Yes.
Q Okay. And your clients then typically are

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pharmaceutical manufacturers or companies who are somehow involved in the pharmaceutical industry?
A Yes.
Q Have you been -- well, when you're hired by a company to engage in regulatory consulting as you've described it, tell me how you would kind of approach that engagement.
Tell me the steps that you would undertake in a typical engagement if somebody is hiring you -- let's say, for example, a company hires you to determine regulatory compliance, whether they are in compliance with Good Manufacturing Practices.
How would you undertake that engagement?
A What I would do first is define the scope of work, what do you want me to do, because the way that is presented, get us in compliance, that could range anywhere from two days to two years.
So as with any project in any field, define the scope of work so that you're doing the proper thing for the customer. The reason I say that is a customer might say, I have another consultant doing computer validation. Good. You don't want me to go near your computer validation.
But I want to look and say, all right, what do you want me to do? Analytical methods. How many? Let

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me see which ones they are. Do you need any developed? Do you want me to review them? What do you want me to do? Then I will look at them. And it could be -- and I'm making this up to answer your question right now.
Q Understood.
A It might be, I've got to be at your firm and watch this being done. You have the method. It's not working out. I have to be there to see -- meet the analysts and see who's doing it. Vastly different in time and money than sending it as an e-mail attachment and having me read it.
Q Okay.
A So I want to look at that and then put a proposal to the client as to the job as I perceive it is review the following methods. I will come to your facility for two days and work with your analytical chemists. Then I will go back to my home base and write a report.
In some cases it might just be, we'll send you the methods and tell us if they're in the proper format. So getting to your original question, I would first define the scope of work and then give them a proposal as to how I would go about it to get their authorization for it. And then we proceed from there.
Q And once you -- and once you provided them

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the proposal and defined the scope of the project as you've described it, if you were asked by a company to determine whether a certain product had been manufactured and released in compliance with Good Manufacturing Practices, would that involve document review?
A Yes.
Q What types of documents would you review in the context of that analysis?
A Could I have that question again?
Q Yes. I asked you if you would review documents in order to determine whether a certain product had been manufactured in compliance with Good Manufacturing Practices and you said yes.
A Yes.
Q What types of documents would you review to undertake that analysis and advise the company whether they then -- whether that product had been manufactured in compliance with Good Manufacturing Practices?
MR. MILLER: And I'm going to object. It's an incomplete hypothetical. But it's okay to answer.
A For a thorough answer to your question, or a thorough part of -- again, defining the work, I would

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say to the client, well, what I want to do, I want to see -- are you having any problems anywhere? Are you having problems with new analytical chemists that are having problems with their answers? I try to define it more specifically.

And -- but typically it involves going back to all the procedures from raw materials coming in, in process materials as it is being produced and the testing that's associated with it and the finished goods released.

I want to see the whole workload from raw materials in to finished product out. That's what I want to see. And I also want to see -- and it's very important -- the training records of the people involved in doing it to make sure they're qualified.

Q So you want to see -- if I understand correctly, you want to see all documents associated with production of that product?

A Yes, I do.

Q And you want -- and then you review them and develop your opinion as to whether GMPs have been complied with or not?

A Yes, I would. I want to put it in a proposal first --

Q Understood.

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A -- so that the client knows the time and their money involved and they don't try to get me to short-cut something. So you have to be thorough in things. And I want them to know the degree of thoroughness and the amount of time and energy it will take to do it.

Q I understand. But in order to be thorough and to properly advise that client about whether that product had been manufactured and released in compliance with Good Manufacturing Practices, you'd tell them up front so that they wouldn't be surprised at how much time and cost might be involved that you need to require all of the records you've just described -- or I'm sorry -- you need to review all of the records that you've just described. You'd tell them that up front, correct?

A Yes, I would. And it wouldn't surprise them. They usually expect me to say that.

Q Okay. What if they didn't want you to review those records? Could you do the analysis that I've just described?

A It is quite likely that I could not and I would not accept the project.

Q Okay.

A I might just say, you don't want me, you

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want someone else, I can't do it under your constraints.

Q Okay. Have you ever been deposed before?

A Yes.

Q How many times?

A In the last four years twice.

Q Tell me about those two times.

A Can I refer to my report?

Q Actually -- to your report?

A It's --

Q Your expert report?

A The depositions are in the report.

Q Yeah. Let's do this a little differently, though, because I've actually got that marked as an exhibit, so -- and if you can -- you can go ahead and put those off to the side. I'm going to review those when we get a break. But I --

A All right. If you have the two cases --

Q I do.

A -- that will be fine.

Q Okay. So, Mr. Farley, I have handed you a copy of a document. And we've pre-marked our exhibits. You might have heard a little bit of that exchange as we were getting ready to go on the record this morning. So the numbers aren't going to go sequentially necessarily. If we mark new exhibits we'll make them somehow

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sequential. But this document has been premarked as Exhibit 45.

A Can I write on this? It's dark.

MR. MILLER: No.

Q No, you can't.

A I'll just remember 45. I'll remember it.

Q Yeah. Well, we'll remember that it's your report. Will you take a moment just to look at that document and confirm that it is the report you were referring to a moment ago, your expert report in this case? And I will tell you in advance that we have taken your CV off the back. We'll make that a separate exhibit.

A That's my report.

Q Okay. So Exhibit 45 is the report that you prepared I assume at the request of Plaintiffs' counsel in this Digitek litigation and it's the report you were referring to when I asked you to identify the -- or you were about to review and refer to when I asked you to identify the times you've been deposed in the last couple of years, correct?

A Yes.

Q Will you -- so let's go back to my question. What are the times you've been deposed? You said you've been deposed twice.

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A In the last two years.
Q Okay.
A I believe I was several years ago, but it's vague in my memory. But these are the more recent ones and they're on page 4 under background.
Q Okay. And so I see two cases listed here. One it looks like Chanin versus Desert Shadow Endoscopy Center. Tell me about that. What was the nature of your involvement in that litigation?
A I heard the question. I'm trying to think of --
Q Take your time.
A I'm posing my answer so I know where to start and get right to the answer.
Q I appreciate that.
A There was -- there are a couple of endoscopy clinics all under the same ownership in Las Vegas. And there were a combination of factors. They were multi-dosing Propofol when they would sedate the patients for endoscopies and other such procedures.
And they were accused of -- I say -- I'm pausing about the word alleged. It's been proven. So I'll knock out the word allege.
They were taking Propofol from a large container, giving it to one patient and taking a little

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more, giving it to that patient and then taking some and giving it to another patient. In the course of doing that several patients contracted hepatitis.
Teva and Baxter, the manufacturer and distributors, were involved in that they were selling the large units where a purchaser like an endoscopy clinic could get a discount price and were selling it to a clinic known that they only needed the little vials.
And while I'm pausing, because once I did my work I'm speculating what came after, but the court judged that, yes --
Q And I apologize for kind of cutting you off. Can you just describe for me what your involvement in the case was? Generally what were you engaged to review and what was the general subject of your opinions?
A Thank you for that. I was pausing because I wasn't sure --
Q Yeah, yeah.
A -- this or that what the Court said when I wasn't there.
Q At least initially I'd only like to hear your involvement and what your opinions were. And then I'll decide whether I want to ask more.
A That's what I can answer most

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intelligently.
Q Okay. Excellent.
A My involvement was looking at the labeling of the Propofol and the manufacturing of the Propofol and rendering an opinion in that regard. Does that answer your question?
Q It absolutely does. And does that mean that your involvement in that case did not touch on -- you weren't asked to give an opinion about regulatory or GMP compliance in any aspect?
A With regard to the labeling.
Q Not with respect to production or manufacturing or analytical or laboratory related GMPs?
A Not to any major degree.
Q Okay. The next case listed here, Olson versus Septodont, tell me about your -- again, what was your involvement? What were you engaged to give an opinion on in that case?
A In one respect it was a similar case. It just happened to be. A lady in the Tacoma, Washington area who was a dental patient was given Septadine by her dentist. And the reason for that is to numb the gum area while the dentist did his work.
But she -- I'll use the word overdosed, but I'll put it in quotes, because I don't want to use

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that -- too much was given. And she -- it ruined her nerve. Her face sagged. She has trouble talking. It was irreversible what happened to her. And we looked at manufacturer, industry and the labeling aspects of it, including directions.
Q And when you say we, do you mean you?
A Oh, me. There were no other chemists to my knowledge. At least I didn't meet any. We meaning my client, the lawyer.
Q So what type of compliance issues did you give an opinion about in that case? Do you remember?
A Labeling plus the responsibilities of a generic manufacturer.
Q With respect to what?
A With respect to labeling, extra labeling, putting warnings on, giving notices, keeping track of who buys it.
Q Okay. So that was -- your involvement in that case was fairly narrowly limited to labeling and related issues?
A Yes, uh-huh.
Q Let's go back to your time at the FDA. You were there from 1989 until 1996? Does that sound right?
A Yes.

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Q And you said -- your background -- well, first things first. Your background, your educational background, is in chemistry, correct?
A Primarily. I have a master's degree in physio-chemistry, but then I went on to get an MBA in financing and marketing.
Q Okay. And when you were at the FDA you were initially hired as an analytical chemist?
A Yes.
Q How long were you in that position?
A By title, about three years; by assignment, about one year. The district director of the Philadelphia district and the regional director of I think four districts at that time, Baltimore -- it's been rearranged. It's vague now.
But the regional director knew that I had experience in the pharmaceutical industry. And they had some things they wanted me to help out with, like getting the samples out more on time and looking at some things that -- I'm pausing because I don't want to say anything negative about government employees.
But there were some mindsets there of this is the way we've always done it. And as one of my bosses said to me, you're breathing a breath of fresh air in here letting us get done what we want to get done.

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And just helping them like, why are you doing this when you should do this, little management assistance but I was still classified as an analyst. But I would travel to the Baltimore lab and the Cincinnati lab as in effect the person who was sent by the regional director to work with them to improve their procedures.
Q Does that mean that you were providing guidance or insight with respect to what I'll characterize as efficiency issues?
A Yes.
Q Okay. And you say that started after about a year?
A Yes.
Q It lasted how long?
A Up to and including when they promoted me to be director of the science branch, which is in effect the laboratory director.
Q Okay. And that was after three years, after you've been at the FDA for three years?
A Three years, three and a half. Three. Just say three.
Q Okay. You were there a total of about eight years?
A About eight.

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Q When you became director of the lab I take it that means you jumped over a couple levels of supervisors to go from an analyst position with those kind of efficiency responsibilities directly to the director of the lab.
Does that mean you jumped over a couple of levels?
A Yes. Some people I worked for were then working for me.
Q That's always fun.
A It was.
Q Tell me what you did as director of the lab.
A With 30 chemists in the lab I was responsible for all of their functions. I worked through two supervisors. There were two supervisors who reported to me. But I knew everyone in the lab on a first name basis.
But they had to get their analytical work done, their analytical work of samples that were taken and brought in from pharmaceutical firms. They had to do that.
They did some analytical methods development and they had to accompany the inspectors on the inspections. An inspector is an investigator, is a

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consumer safety officer. They were all the same. Consumer safety officer is their designation, CSO, but we called them inspectors or investigators.
When they go on an inspection they want one or more chemists with them to be more knowledgeable about the scientific aspects of their investigation. An investigator -- I've known investigators that had Ph.D.s in science and I've known others that had 30 credits in science.
The ones that -- the ones in inspections, they know what they're going to be looking at. And if they don't know initially they see when they get there and they'll call and say, I need a chemist who's knowledgeable about this or this. Okay, send them up.
So participating in inspections, assigning the proper chemist and doing the scheduling to make sure that the work flow in the lab is always done. This was all part of the job of running the lab.
Q Okay. So typically you weren't the person who was in the field involved in FDA inspection, correct?
A I was as an analyst accompanying investigators in the scenario I just mentioned.
Q Well -- okay. So as an analyst you mean during that first year of employment before you started

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traveling to other labs and counseling the FDA regional offices or district offices on efficiency?
A And during the second and third year. When needed, when they needed me.
Q How often?
A It's tough to pick an average. You might go two in a row and then none for a couple months. It's difficult. If I said a few, would that be too vague?
Q Well, if you give me a better sense of a few. You were in that position for -- as an analyst -- let's break this down a little bit. As an analysis you were in that position for three years.
A Yes.
Q During those three years did you participate -- and by participate I mean go out and actually -- where you were actually on site, not involved in scheduling and deciding who goes and things like that, but where you were actually on site how many inspections would you say you were involved with during those three years?
A I'm drawing on my memory now.
Q All I can ask you is to the best of your recollection.
A One quarterly.
Q One quarterly. So that's perhaps a dozen

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in three years?
A Yes.
Q And you weren't necessarily on the premises for each and every day of all of those inspections, right? You were there as needed?
A Generally as needed. The inspectors feel comfortable having you there every day, but the workload doesn't always permit it. They really feel comfortable having one or two scientists around. But you get there. You do your job. What do you want me to look at? What do you want me to evaluate? And then you -- that's it.
Q When you became director, so during that last five years, how many inspections were you involved with by actually -- and by involved I mean actually on the premises during the inspection.
A I wasn't assigned directly because it wasn't my primary area of responsibility. However, in -- I should say the Philadelphia district included Pennsylvania and Delaware. And the laboratory covered Jersey because they didn't have a lab.
I would not be assigned to go on any of them. But I would on occasion say, I'm going to drop in on such and such a day and just walk through with you. And that might be to Merck or what was then SmithKline Beecham -- it's now GlaxoSmithKline -- just to make sure

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that everything was going along well.
Q So participating in investigations or inspections in the field was not something you did regularly?
A You could say that, yes.
Q How many -- you mentioned earlier and I believe your report references it as well. How many warning letters did you issue while you were employed by the FDA?
A I signed?
Q Well, let's break that down a little bit. How many -- let's ask that question first. How many warning letters did you actually sign?
A I might have only actually signed one. I was involved in the input of various -- our district director signs the warning letter.
Q How many -- well, did you draft that one warning letter that you signed?
A No. It's drafted by the investigation staff and then brought to you and you -- that is a document that before you sign you read every word. It's not a glance at and sign and get it off your desk type of document, not to imply that the federal government has any like that. But you read every word because of the severity of it.

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Q Well, but there's a difference between reading it and having an understanding of it and actually drafting and having input, correct?
A Yes.
Q And as director of the lab you weren't responsible for drafting and developing warning letters, were you?
A No.
Q And in fact, the one that you signed you signed only because you were in some sort of acting capacity outside your lab director position?
A It was while I was still a lab director, but when the boss would either be on some -- maybe down at headquarters for a meeting or on vacation he might just say, Jim, take my place as district director for this week. And I might say, well, Boss, what have you got coming in? And he might give me a rundown of what to expect.
Q So that made you essentially acting district director?
A Yes.
Q And that's why you signed that single warning letter?
A Yes.
MR. ANDERTON: Are you sharing one with

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him?
MR. MILLER: It looks like I am.
MR. ANDERTON: Okay.
THE WITNESS: Okay.
MR. ANDERTON: Actually do you need one while we're --
THE COURT REPORTER: Not while we're doing this.
MR. ANDERTON: Okay. Thank you. So the ones that we give Mr. Farley can go to Angela.
BY MR. ANDERTON:
Q Mr. Farley, I've handed you a document. And I know the exhibit stickers perhaps are difficult to read. But it has been marked as Defendants' Exhibit 44.
A Yes.
Q Can you just take a moment to review that document, please.
A That's me.
Q Okay. Is that an accurate copy of your CV?
A Yes, it is.
Q It's the one that you actually attached as Attachment A to the report that you prepared in this case, correct?
A Yes.

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Q I think I asked you this earlier. You're not a medical doctor, correct?
A I'm not a medical doctor.
Q All right. Is it accurate to say that your expert opinions in this case are limited to opinions about whether Actavis was in regulatory compliance with Good Manufacturing Practices?
A Yes.
Q You're not offering any opinion about how any -- whether -- let me start that over.
You're not offering any opinion about whether any specific consumer or patient got or received and took product that was defective?
MR. MILLER: Object to form of the question.
A I'm not sure I'm understanding your question the way it's worded.
Q Let me see if I can ask it more clearly. Is it true that you're not offering an expert opinion about whether a patient in the market received a defective Digitek tablet?
A I wouldn't know if a patient in the market received a defective tablet unless I was told or saw data. Is that --
Q Well, so then -- but you need to answer my question, Mr. Farley. You're not offering an opinion in this case about whether any consumer received a defective Digitek tablet, correct?

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MR. MILLER: Object to the form of the question.
A I'm thinking the way it's worded, I read that a consumer did, but I don't have an opinion on it.
Q Well, so I need to be clear then. You're not offering an opinion on that subject, correct?
A As to whether a person taking a particular medication received it or not?
Q Correct.
A I have no idea who took it.
Q Okay. And you're also not offering any opinion about how specific patients react to specific doses of Digitek, are you?
A Not a professional or an expert opinion. There are things you know about certain drugs from being in the industry 40 or 45 or more years, but not who would be prescribed. I don't prescribe.
Q Well, all right. Again, I want to make clear. In the context of this case and this litigation you're not offering any opinions about how any patient reacts to a specific dose of Digitek; is that correct?
A Not with regard to a patient, no.

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Q Okay. Have you ever been a defendant in a lawsuit?
A I'm pausing. I should know, like would know, but I'm -- in order to answer your question correctly, no, I have not.
Q Have you ever actually testified -- we've talked about the times you've been deposed. Have you ever actually testified in court?
A Not as a consultant. When I was with the FDA -- and that was not a case such as this. That was an EEO case since I was chairman of equal opportunity at the same time.
Q So it was an employment case, not a regulatory and -- not a case that had anything to do with regulatory compliance?
A Correct.
Q Any other times? Have you ever testified any other times?
A I did not. They all settled. I would be glad to do it, but they just -- the attorney, my client, would contact me and say, we settled the case, send the final bill. And that was it.
Q How did you prepare for this deposition?
A During -- off and on. During the last several weeks I would receive documents from Miller Law

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Firm, specifically Pete Miller. And I would review them. And when I received notice about a week ago that this deposition would be today I said, how about if I review my reviews. And that's what I did.

Q And the documents that you said you reviewed over the last several weeks, what documents were those? Well, let me make that question clearer.

The documents that you said you received from the Miller Firm over the last several weeks, I believe is your terminology, what documents were those?

A They would include EIRs, Establishment Inspection Reports; 483s; warning letters; a revised warning letter; various documents within a firm; charts of regulatory activity; some current Actavis correspondence, internal and to the FDA; the request for consent decree; the consent decree itself.

They would all come in binders and a binder might contain a variety of document -- would contain a variety of documents. That's what.

Q When did you start receiving those documents, those binders of documents?

A I believe the first binder arrived in January. Then -- I reported on that and then there was a space in time and then another binder arrived in April.

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Q When you say then you reported on that first binder, what do you mean by you reported on that?

A Wrote a brief report on my evaluation --

Q Of that first binder?

A -- of the contents of the first binder. Yes.

Q And what became of that brief report regarding the contents of that first binder?

A I sent it to Pete Miller at Miller Law Firm.

Q Do you have that first report on that first binder with you today?

A I've got it on a thumb drive.

Q Thumb drive. I was --

A There was only so much I could fit in suitcases.

Q And having read one of your prior deposition transcripts I know that you use the thumb drive. So that's on my list of things to ask you today, believe it or not.

We will definitely want to take the thumb drive and -- or somehow get the documents that are on that thumb drive that relate to this litigation in our possession. Okay?

A Yes.

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Q And in fact, it occurs to me I might want to see those today before we leave so that I can determine whether I want to ask you any questions about that.

A Yes.

Q So we'll work on that during the break somehow. Okay?

A Fine.

Q How many binders total did you receive from -- well, did you receive documents from anyone except the Miller Firm?

A I'm thinking. I heard your question.

Q Take your time.

A I'm thinking to give you an accurate yes or no on that.

Q I appreciate that very much.

A No, only the Miller Firm.

Q How many binders or -- how many times did you receive documents? Perhaps they weren't always in binders. How many -- how many shipments of documents did you receive from the Miller Firm?

A A total of five binders. There may have been two in one shipment. So my answer is it's definitely binders and likely to be four shipments.

Q Okay. Are the documents -- and did you

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review all of the documents in those binders?

A Yes.

Q Are the documents you reviewed -- now, I asked you initially what you did to prepare for this deposition and I think we've kind of transitioned to what you did to prepare your report.

Is that a fair characterization of what we're describing now when we're talking about all of these binders received over what sounds like a five- or six-month period?

A Yes. That was -- I had the initial binder and then wrote a report on -- in February, I believe February 5th. And then later on more binders arrived. So I reviewed them and I wrote another report.

Q So you wrote -- did you write a report in response to each binder that you received?

A Not in response to each binder. I just in effect kept building up the original report.

Q Okay.

A I took the original report and just expanded the table. But each document has an individual review electronic file on my thumb drive.

Q Okay. So each document then has a -- I take it then that there are documents on that thumb drive that reflect your specific analysis and perhaps

comments regarding each document that you reviewed?
A All 93 of the -- all -- some were duplicates in title but had different redactions.
Q Okay.
A So there may have been roughly 80 to 85 different documents. I had a total of 93. And in some cases here's a 483, here's a 483 I received two months ago, but there are different redactions. I can see more or less. So I'm saying 93 documents and -- 90 to 93. But each one is a file on the thumb drive in my pocket.
Q Okay. Well, that's going to speak to the viability of my reviewing those documents on a break today. And unfortunately it may also speak to whether we have to reconvene, leave the deposition open and have a second session. But those are decisions that we'll make as we kind of move through the process.
MR. MILLER: While we're on that topic, I brought a hard copy of everything he's talking about and you're certainly more than welcome to take a look at mine.
And although it sounds quite lengthy, it's not as lengthy as you would think. I wasn't anticipating the thumb drive. So I brought a copy for me.
So being the great guy that I am I'm



going to offer up the copy that I brought so you can read them at lunch in hopes of possibly wrapping this up.
MR. ANDERTON: Okay. Well, I appreciate that and we'll certainly take a -- at least an initial run through it and we'll decide from there.
I mean, I apologize if there's an inconvenience involved, Mr. Farley, but I hope you understand, you know, we have to see what's out there and then react accordingly.
THE WITNESS: There's no inconvenience. That's what we're here for and that's why I brought the little computer and the thumb drive.
MR. ANDERTON: I'm actually talking about the possibility of reconvening and having at least a partial second session, you know, if I decide that we can't get it all done today and if we need a little time to review those documents. But we'll make those decisions as we move through the process.
THE WITNESS: Your choice.
MR. ANDERTON: Excellent.
BY MR. ANDERTON:
Q So then you said you kept building up the



report. Does that mean that you would characterize each of these reports as drafts that led up to the final report you issued in this case?
A No. They weren't intended to be drafts. I might prepare a report and save it as a file on my thumb drive and the C drive, the C drive of my PC in my home office.
Q Right.
A And then I'd review it a couple days later and I might say, oh, well, I looked at more references than that, I looked at the Physicians' Desk Reference, I looked at this. And I would, upon thinking about it, add more to it.
But then I felt I can't keep it as the same document. I added to it for the reason I just mentioned. I'll save it as a new document. And I usually did that just by the date.
Q Okay. Okay. The 90 or so documents that you said you reviewed, some duplicates or others with different redactions and such, are all of those documents listed in your report as documents that you reviewed?
A Yes, they are.
Q Are there any documents that you reviewed in order to prepare your report that are not listed and



identified in your report?
A My offhand answer is no.
Q Are there any documents that you -- and did you review every document that you received from the Miller Firm?
A Yes.
Q Are there any documents that you received from the Miller Firm that are not listed in your report?
A No.
Q The thumb drive that you have today that we're going to do something with, are there any documents that relate to your engagement in this litigation that are not on that thumb drive, stored somewhere else perhaps?
A Documents that relate to this -- I'm pausing answering the question because I would go to the FDA Web site and look at certain things to make sure I had the proper definitions.
I would look at some slides and presentations that I've done in lectures to make sure that I said the same thing or that I wasn't misleading any readers. But not counting that part my answer is I reviewed every document. There's nothing that I received that I didn't review.
Q Well -- and I guess I want to make sure.

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Are there any documents perhaps -- you identified what you don't want to call drafts, but various versions of your analysis of various documents.

Are there any of those documents that you prepared, analytical type documents, that are not on that thumb drive?

A I'm thinking. My answer is no.

Q Okay. So every document that reflects your analysis of the materials you received as part of your engagement in this litigation, notes and everything is on that thumb drive?

A Every document?

Q Yes.

A I'm pausing again because I would go to the FDA Web site and look just to make sure certain definitions. I would look at some of my other work, the slides from lectures that I've given, to make sure that this is what I said and refresh my memory.

And they're on the C drive and not on here. But what I call official documents relevant to the case, my answer would be no. There's nothing -- maybe we ought to go back to the question again.

Q Yeah.

MR. ANDERTON: Can you read that back, please?

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(The record was read back as requested.)

BY MR. ANDERTON:

Q And the key there, Mr. Farley, is documents that reflect your analysis or your work product.

A Documents. I'm -- then my answer is everything is on there.

Q Are there -- are your notes on there? Did you take notes? Let's start with that. Did you take any notes as you -- you know, you've described reviewing documents, preparing some sort of report on that review.

Did you first take notes before you prepared the review?

A I might during a review just jot something down, a word, a key phrase, and then I type the review. And I look down, word or key phrase, sometimes to make sure I got the word itself right and sometimes maybe just a spelling. And then I type it, it will look good, and at that time toss the notes out, because that's all they were for.

Q Okay. So you didn't keep any of those notes?

A I did not.

Q Do you -- did you mark up or write on any copies of the documents you received from the Miller Firm?

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A Yes.

Q Did you bring those marked-up copies -- well, did you keep those marked-up copies?

A Everything is in the case, the black suitcase and/or the tote.

Q Okay. So if you wrote up -- wrote on or marked up a document that you received from the Miller Firm and -- or as you reviewed it, that marked-up copy is with you here today?

A Yes.

Q Okay. Have you ever been involved in any consulting -- have you ever provided consulting services that related in any way to the manufacture of Digitek?

A No.

Q Ever been involved in any case that related to -- that related to Digitek in any way?

A No.

Q Did you review the Digoxin product label in this case, the Digitek product label?

A I'm not sure. I really just don't remember.

Q You don't remember because you don't remember that it was -- whether it was one of the 90 or so documents you received from the Miller Firm or just

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don't remember?

A Once I knew that was a product that was either this case or part of it, I would look in the Physicians' Desk Reference to -- I will look at the molecule. I would want to learn more about it, what it's used for, various aspects of it. I would do that.

Q Other than the Physicians' Desk Reference what other medical literature did you review to prepare your report and the drafts -- or not -- I'm sorry -- not drafts but the different reports you prepared along the way?

A Can I look in the report?

Q You certainly may.

A Some of them I could tell you offhand, but for accuracy I think I better read the report.

Q Please. Mr. Miller will tell you I'm a slave to accuracy.

A That's what it's all about. Why be here if we're not going to be accurate?

Q I couldn't agree more.

A On page 16 and carrying over to page 17 --

Q And so that we're clear, Mr. Farley -- I apologize for interrupting you. But you're talking about pages 16 carrying over onto 17 of your report?

A Dated -- my report dated June 14th.

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Q Your final report?
A Yes.
Q Is that a fair characterization?
A Up to now it is my final report.
Q Okay. Well, you say up to now. Do you have any intention of revising it?
A Not on my account, not unless you say so. No, I don't have any intention to revise it.
THE VIDEOGRAPHER: Mr. Michael, I need to go off record and change tape, please, sir.
MR. ANDERTON: Okay.
THE VIDEOGRAPHER: We're off record at 10:09.
(A brief recess was taken.)
THE VIDEOGRAPHER: It's 10:18 a.m. This is the beginning of Tape 2 in the deposition of James J. Farley.
BY MR. ANDERTON:
Q Welcome back, Mr. Farley. Thanks for coming back. You were I think when the tape ran out giving testimony about information on pages 16 and 17 of your final report. And I guess I just want to ask one final question or maybe two.
But the medical literature and other references identified in -- or on pages 16 and 17 of

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your report, in your mind is that the total -- is that the complete list of resources other than documents you received from the Miller Firm that you reviewed in order to prepare your report?
A I'm thinking here. I'm relying on my knowledge, looking at perhaps some of my presentations, because I do instructional training that are not -- these are books or what we would generally classify as documents.
So if I say yes for the documents, I would like to have as an exception from that any lecture materials I might have used, because I flip through them and look real quickly to check something, put it back and I just didn't write it down.
Q What -- well, then let's test your recall. What of your lecture materials do you recall reviewing as part of your work in this case?
A Among others, it's called CAPA, C-A-P-A, Corrective Action/Preventive Action. That's a program within the GMP, Good Manufacturing Practices structure. I looked at that.
I looked at forms that I designed for clients on how to handle deviations, forms I designed for clients on how to handle out of specification results. I looked at a lecture I gave on root cause analysis,

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which is part of deviations and out of specifications results, all under the Corrective Action/Preventive Action umbrella within GMPs.
I would flip to them, just take a quick glance and didn't bother noting it on here. But -- and there's any number of things. That's just part of it.
Q Okay. And if we -- and I'm not saying that we definitely want to, but if we wanted to ask you to go back and identify and produce as many of those as you could definitively identify as something you reviewed as part of this case, you could do that?
A I could do it.
Q Okay. For at least some of them, I presume?
A Those that I remember --
Q Right.
A -- and those that you want, yes.
Q Okay. Going back a little bit, we talked about what you would do at the beginning of a typical engagement for a pharmaceutical company. And I believe you said that you'd want to gather some additional -- not additional, gather some initial information and then prepare what you described as a proposal so that you and the prospective client are on the same page about the scope of the engagement.

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Do you remember that testimony?
A Yes. Yes, I do.
Q Did you do that in this case?
A I wasn't called by Actavis to help Actavis.
Q I understand. You were contacted by Dr. Smart, who apparently had the front end or direct initial contact. But then you were contacted by Mr. Miller or somebody from his firm within a day or two after that, correct?
A Yes.
Q Did you talk to Mr. Miller or someone from his firm about the scope of your work or potential work in this litigation and did you prepare a proposal and submit it to him?
A I didn't prepare a proposal and submit it in this case that way, because my discussion with Peter Miller, as I was getting ready to ask the questions, he said, I have a binder of documents I will Fed Ex to you. To which I said, what does it have in it? Does it have 483s, anything like that? And he said yes.
Fine, send me the documents, I will look at them and then determine what questions I have. Jumping for a moment, if I may, if I were going in to help a firm and defining the scope of work, I would say to the

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firm, I want to know the results of your most recent internal audit and I want to know the results of the most recent two FDA inspections that you have. And that would give me a feel.

I didn't have to ask that in this case, because when Pete Miller and I talked on the phone and he said, I'll send you documents, I'll Fed Ex them, okay, I'll look at them and then see, the questions that I normally would have asked were answered by the documents that were contained in the binder.

Q Okay.

A Did I put it in the proper perspective?

Q Yes.

A Okay.

Q You've described four shipments containing perhaps five binders of documents --

A Yes.

Q -- all selected by Mr. Miller or somebody on -- associated with Plaintiffs' counsel, correct?

A Yes.

Q Did you ask for any specific documents other than those that you received from Mr. Miller in these binders?

A As we went along when I received the first binder -- let me start with the first binder, which had

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25 tabbed sections. And it had Establishment Inspection Reports, 483s, various things on the list here in the report.

And I would start reviewing them and preparing the individual electronic files, the ones that are on the drive, on them. And then I would call Pete Miller and say, here's what I've got, do you have such and such, do you have this.

And the answer might be, we're in the process of getting them for you, keep working on what you've got, when we get them we'll send them to you. So there was dialogue intermittently all along.

Q Was any of that -- did you make any of those requests in writing?

A No.

Q E-mail?

A Maybe e-mail.

Q So you did have e-mail communication with Mr. Miller or with somebody from his firm starting during the period let's say December 2009 through today? You've have e-mail communications?

A Yes.

Q Do you have those e-mails?

A I did not print them out and bring them here. Much of it was scheduling or when to expect

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another package. All my results I would confine to the reviews, the individual reviews, each of which is the electronic file, and to the report.

Q Are those e-mails on that thumb drive?

A No. I just didn't think to save them, because --

Q Well, I guess I want to make clear, you just -- a moment ago you -- the concept of saving them. Do you still have those e-mails?

A Not saved, per se. If someone went into my PC in the home office they would probably find them. But they're not where I could pull them up.

Q Okay. Are they -- I take it you have -- what is your e-mail account?

A AOL.

Q Are they just in your AOL in-box somewhere?

A 30 days --

Q 30 days.

A -- and then --

Q So your belief is any e-mail that you would have received more than 30 days ago you no longer have?

A Correct. But can I add something to that?

Q If you like.

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A If it was an e-mail that I perceived had direct relevance to my evaluation of the data, I would have saved it and printed it out. Much of them were I might get something from Nia saying, Pete's out of town, he'll get back to you in such and such or --

Q From whom?

A Nia, N-I-A, last name Barton, B-A-R-T-O-N.

Q And who is that?

A She is either a secretary or paralegal to Pete Miller. And there was some scheduling. I might send an e-mail, Pete, do you know when the deposition will be scheduled, simply for scheduling. And since it was scheduling and in my mind they had no basis for my evaluation of this case, I didn't bother saving them.

Q Okay. When you asked for additional documents, did you ask for any Digitek batch records?

A Yes.

Q Did you get them?

A I got one, the batch in question, I believe.

Q Okay. So let's make that clear. As I read your -- the list of documents in your report, did you get a batch record or did you get records that relate to that batch? And you understand the distinction?

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A I understand the distinction. I got batch records.
Q You did?
A Yes.
Q Okay. So you saw the actual production. Was that batch record contained within a larger investigation report?
A No. That is one I got by e-mail. And I downloaded it and I have it on my file.
Q Okay. Do you happen to recall off the top of your head that that is Batch 70924?
A Since you've named it it rings a bell, and I believe that is it.
Q Okay. And when you said the batch in question a moment ago, do you mean the batch where during manufacturing some tablets that were defectively thick were found?
A Is that 70924?
Q 70924.
A Yes.
Q So the batch you asked for and received, one set of Digitek batch records, and that is the records that relate to the batch that had the -- what people have commonly referred to as the double thick tablets?

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A Yes.
Q Is that the only Digitek batch record you reviewed as part of your engagement in this litigation?
A Yes.
Q Is that the only Digitek batch record you received as part of your engagement in this litigation?
A Yes.
Q Mr. Farley, I've handed you a document that has been marked as Defendants' Exhibit 74.
Have you seen that document before?
A Yes.
Q That's a notice of the deposition here today?
A Yes.
Q And attached to it if you go all the way back -- it should be attached but is not. Oh, I'm sorry. It's in the -- on the first couple of pages. You see there's a list of documents that you are requested to produce?
A Yes.
Q Did you read that list before you came here today?
A Yes.
Q You're showing me a copy that has check marks on it and that is marked up.

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A And I made little notes of what -- the proverbial thumb drive.
Q Okay.
A That's what --
Q You know what?
A You want it?
Q I do.
A You can see it.
Q I do.
MR. ANDERTON: Can we mark this? And we're just going to mark it 74A, the follow-up practice of Mr. Moriarty. I don't like it but --
MR. MILLER: Wouldn't it be 74B? You wouldn't call it A. You'd call it 74B.
MR. ANDERTON: I said it's not my practice, so --
MS. DOWNIE: Well, we have 74, right?
MR. ANDERTON: Yeah, we have 74.
MS. DOWNIE: And then we would have --
MR. ANDERTON: But we don't have 74A.
MS. DOWNIE: And then 74A.
(Defendants' Exhibit No. 74A was marked.)
MR. MILLER: Not to mention we jumped from 45 to 74.
MR. ANDERTON: Well, Pete, I warned you

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about that.
MR. MILLER: Yes, you did but I still had to throw it in.
THE WITNESS: Was there anything attached to it? I handed you everything without looking at what might be behind it.
MR. ANDERTON: Let me take a look and we will only mark --
MR. MILLER: There's another copy of the report.
MR. ANDERTON: Is it the final copy?
THE WITNESS: June 14th?
MR. ANDERTON: Does it say June 14th?
MR. MILLER: The second page in the first paragraph.
THE WITNESS: If that says June 14th that's the extra copy I printed out for anyone who may need it.
MR. ANDERTON: Well, the copy that I have -- I thought it had the date right on the front. It does. Oh, this one does, too.
THE WITNESS: Left side, lower left.
MR. ANDERTON: So I'm going to give that back to you and we're going to mark only the notice that you took and -- or that you received

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and that you made comments on, or put some notes on.
BY MR. ANDERTON:
Q So anyway, my question, Mr. Farley, my first question is -- and I'm looking at the -- what's been marked as 74A. And I'll give that back to you to hold for a moment.
Is it correct to say that you reviewed this notice carefully?
A Yes.
Q And that you checked your files to see whether you had any documents that were responsive or that were described by the categories on that notice?
A Yes.
Q Have you brought with you today all documents that are responsive to that notice?
A To the best of my eyes those that were available. You see here I put not all e-mails are printed.
Q Okay.
A But in accordance with the way our discussion has been going I will give you a qualified yes.
Q Okay. May I see that just for one second?
A Yes.

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Q I see some notes on here. Category No. 6 asks you to produce all bills that the witness -- that you've rendered to attorneys and law firms.
Do you have those invoices with you?
A On the thumb drive. They're timesheets. I submit timesheets to Nigel and Denise Smart. I e-mail them. The week ends on a Saturday and I e-mail them usually on Monday morning. And that's the way we do it. I don't prepare a specific invoice in this case for Smart Consulting Group.
Q Okay. I see a comment next to -- well, let's stay with the invoices for a second. There's two sets of notes here, one that says 450 and one that says 20,700. Can you tell me what those notes mean?
A Oh, sure. Those notes, it tells me -- that should be 4,050.
Q 4,050?
A That's an error on my part. If I were inspecting me I would write that up because that's a wrong number.
Q That notice would be adulterated.
A I have received for 27 hours' work at 150 -- that's right -- 4,050. I had at that moment 138 hours outstanding, or 20,700 dollars owed to me by Smart Consulting Group.

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Q And does that mean that the total work you had performed as of the time you did these -- had performed as of the time you did these calculations is the 20,700 plus what should be 4,050?
A As of the time I wrote them. And if you want to be up-to-date, add 19 hours for last week.
Q Okay. So 19 times 150, that's just shy of 3,000 dollars, if my math is correct. Let's call it 2,850.
A Yes.
Q Plus 4,050, plus 20,700?
A Yes.
Q Okay. I see a note on here that says with respect to No. 5, retainer agreements. You've got a verbal agreement with the Smart Consulting Group? Tell me that about.
A Well, I have a confidentiality agreement with them. But Nigel will just call me up and say, Jim, are you available for a project? What are you talking about, Nige? I mean, we've known each other for a dozen years now.
What are you talking about? Well, it involves this, it involves this, involves this. Okay, fine, it sounds like I've got the time for it, let's pursue it, who should I call or who should call me. That's the way

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we work it, as I do with some other consulting firms, too.
Q When you said a moment ago it sounds like you've got the time for it, is that the only consideration you used to determine whether you're going to take an engagement like this one?
A No, it's not the only consideration. It would be the engagement itself. But if I didn't have the time for it, I couldn't handle it and it wouldn't be fair to tell them I could.
Q I'm looking at another document that was part of the stack of documents that you gave me. And before I mark this, it looks like it's a resume' but it's not labeled the same. And I can look at it and initially see that it might -- sorry for --
A That's okay. That's all right.
Q Is this the same thing as the CV that you attached to your report?
A That should be essentially the same thing. I may have in the report added my association with the Skidaway Institute of Oceanography here and with Memorial Health, The Cancer Research Institute.
I have affiliations with them, board member of one, safety -- and I believe -- and I'll be able to answer that in another second if I can just look down at

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this.
Q Okay.
MR. MILLER: Take your time.
A Yes. What I did -- this is my CV as I had it on my computer.
Q Okay.
A And since I just finished a three-year tenure on the board of the Skidaway Institute of Oceanography associated with the University of Georgia and since I am now on the institutional biosafety committee of Memorial Health, I figured I ought to put them on there. So this is what I work with. I added those two things to it and put it on the CV that's in the report.
Q The CV then that is attached to the report is essentially updated and current.
A Yes.
Q Is that correct?
A Yes. It's that plus those two things I mentioned.
Q And the date on the bottom of this is April of 2010. I'm going to go ahead and mark this.
MR. ANDERTON: Can you mark that 74B, please.
(Defendants' Exhibit No. 74B was marked.)

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MR. MILLER: Mike, may I see the report?
MR. ANDERTON: You may.
MR. MILLER: Thanks.
MR. ANDERTON: Take your time.
BY MR. ANDERTON:
Q So, Mr. Farley, I'm not going to spend any time on this. What's now been marked as 74B is your CV as it existed as of April 2010?
A Yes.
Q And you've since updated it?
A Yes.
Q When did you prepare the updated resume', or CV?
A As I was preparing the report I just thought, gee, there's something I should add, I've been associated with these two institutions, which are recognized as pretty good institutions down here, and I thought, well, I ought to put them on it. It was that simple of a deal.
Q Okay. I see in your CV a reference to -- hold on one second. If you'll pick up Exhibit 44 with the difficult to read exhibit sticker. All right. On page 24 I see a reference to your taking a course in -- or titled FDA Law and Evidence Development.
A Yes.

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Q Do you see that?
A Yes.
Q Tell me what that was.
A That was two weeks in Bandera, Texas, near San Antonio. And it's a course where certain people, generally if they're grooming you for more things, you go down and you take that course.
You're there in Bandera, Texas, for two weeks. You have your own cabin. You have your own homework assignments working with other students who are FDA personnel from other districts.
And the first week you're taught by FDA people and the second week every instructor is an attorney. All lawyers teach you.
Q Teach you what?
A They teach you the laws associated with evidence development or, as it says, law and evidence development courses. They're not trying to make you lawyers.
They're trying to say from their point of view if you have a sample that you're bringing in, here's the way it is, put the seal on it, make sure that the seal is signed.
They tell you how to handle the sample and other procedures, how to talk to people at firms, the

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associated paperwork to make sure that the Department of Justice would then have a case that would be suitable for court.
Q So it's teaching FDA personnel how to conduct themselves in the field so that the legal staff can use what they collect and identify during an inspection?
A I would say just like you said, but I would not say the field. FDA personnel anywhere, any time, any situation to help the attorneys have a strong case.
Q Okay. You've written two books.
A I have two published. I have some more sitting. I have two published.
Q You've published two books.
A I have had published. They have been published by CRC Press. They're not self-published.
Q I understand. You've had two books published. Is that the best way to say it?
A Yes.
Q Okay. Do either of those books relate to the issues on which you gave your opinion in this litigation?
A No.
Q Mr. Farley, I have handed you a document

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that is marked as Defendants' Exhibit 46.
A Yes.
Q Have you seen that document before? Take a moment or as long as you need to flip through it and determine whether you can -- or figure out whether you can answer my question as to whether you've seen it.
A I'm one of the authors.
Q Okay. So that means, yes, you've seen that before.
A Yes, I've seen it.
Q Tell me what it is.
A Gene Brooks, who owns Brooks Law on York Street in Savannah, and Jim Shipley, who at this writing had just passed the Bar exam and works for Gene, and I thought it would be good to join forces of a chemist who used to work at FDA, pharmaceutical and stuff, and attorneys.
I'm not familiar with Gene's cases, but I'd have to assume that some of them might involve this. So we co-authored this, he quoting the USC, me quoting the 21 CFR.
We each quoted our own -- we brought our own areas of expertise into it. And it was published in Trial Magazine, which is the publication of the American Association of Justice, in November of '08.

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Q And you said a moment ago as you were giving that answer he offered his input on the USC, you on the CFR.
To be clear, that means -- by USC you mean United States Code?
A Yes, or in my words, he talked lawyer talk and I talked chemist talk.
Q Okay. So -- and the CFR -- and I need to be a little more methodical on how we break this down. The CFR you referred to, that's the Code of Federal Regulations?
A Yes.
Q So he offered his input on the law; you offed your input on regulatory issues?
A Yes.
Q You didn't -- you're not a lawyer?
A I'm not.
Q Okay. Do you know whether he represented the law correctly?
A Whether Gene represented the law correctly?
Q Yeah.
A I assume he did. I do not know if he represented the law correctly.
Q Okay. The Food, Drug and Cosmetic Act,

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that's -- if I say the Act will you understand that to mean that I'm talking about the Food, Drug and Cosmetic Act?
A Whenever our subject is general pharmaceuticals I would -- if I hear the Act I believe --
Q Okay.
A -- you mean the Food, Drug and Cosmetic.
Q Okay. I will try to be diligent and use the full name where I can, but if I get lazy and just say the Act, I hope you'll understand by that I mean the Federal Food, Drug and Cosmetic Act.
A The Act is fine.
Q Okay. The Act provides certain minimum standards. We've talked a little bit about GMP compliance and the area where you provide consulting.
GMP, which you have defined as Good Manufacturing Practices, the minimum standards for GMPs are set forth in the federal regulations, correct?
A Yes.
Q And that's the CFR that you referred to a moment ago?
A Title 21, 21 CFR.
Q The GMP regulations are very general, aren't they?

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MR. MILLER: Object to form.
A I would say general. I don't know if I'd say very general. That's -- they're general.
Q Okay. So they don't provide specific details about how every act related to manufacturing, testing and otherwise producing a pharmaceutical product is supposed to be performed?
A They do not. May I say why they don't or would you rather me not yet?
Q Well, the reason they don't is because pharmaceutical companies are required to read and then interpret the regulations and develop their own procedures, correct?
MR. MILLER: Object to form.
A And then they submit them to FDA for approval. And once approved, they must adhere to what they themselves submitted and we like to say do the right thing the right way the same way every time.
That's why that the GMP say you have to do such and such. If you're a pharmaceutical firm you say, I'm going to do it this way, time, temperature, et cetera, and then you submit it. And the FDA approves it.
They approve it on the condition that you're going to do the same thing exactly that way every time

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the way you said, we looked at and approved. And if you ever don't do it that way you're in violation.
Q Okay.
A So that was a lengthy dissertation, but I had to put it in proper perspective.
Q Well, and I just want to make sure because you didn't directly answer the question that I actually asked. You implicitly did, but I want to make sure that this record is clear.
The pharmaceutical companies take the general content of the GMP regulations and they develop their own procedures which provide the precise detail on how they're going to produce their products?
A And then submit it for approval.
Q Well, I need you to answer that question. Correct? They develop those procedures.
A Okay.
Q Is that a correct statement?
A I want to hear that one more time.
Q Is it a correct statement to say that the pharmaceutical company -- a pharmaceutical company that manufactures products in order to comply with the GMP requirements is required to read the regulations and then interpret those regulations and develop its own set of procedures that they believe comply with the

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regulations?
A Yes.
Q And then as you said, they submit their interpretation, their procedures to the FDA for approval.
A Yes.
Q They're required to comply with their own procedures.
A Yes.
Q So when you talk about Good Manufacturing Practices, you're not just talking about the federal regulations.
A Correct.
Q You're talking about the regulations and also any internal procedures developed by a pharmaceutical company to interpret those regulations.
A Yes.
Q And interpretations are not uniform from one company to the next, are they?
A That's a tough one to answer yes or no. Can you reword that? If not, I'll just think a little more and try to give you an answer.
Q Well, if you want me to reword it I'll do my best. When a company reads the regulations and develops its procedures they're not just copying

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something somebody -- another company has done, correct?
A Correct.
Q So every company's interpretation of a certain set of requirements can be different than -- or the specific -- let me start this over.
The procedures a company develops to interpret and apply the regulations can be different than the procedures developed by another company to interpret and apply the exact same regulations.
A If I can explain what I think you mean --
Q Please.
A -- then I can answer the question.
Q Give it a shot.
A If one company, assuming there's two firms making the same product.
Q Right.
A One company selects a primary method of analysis for product release and uses what they call HPLC, high performance liquid chromatography, or a chromatographic method for the purity.
And that method says you will take such and such sample, you will prepare it this way, you will dilute it this way, you will run it in this solvent, you will do this and your answer must be no lower than this percent, no higher than this percent. Fine.

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Now, if another company wants to make the same product but says, I think I'll do an ultraviolet spectrum method, they can develop their ultraviolet spectrum method, which is vastly different than chromatography, but they would have to say, I will take my sample and I will dissolve it this way, weigh it this way, I will scan it between this wavelength and that wavelength, I will do the following calculation. And it must be, for example, 98 to 102 percent done that way.
Each of those could be submitted and could be approved. But each of them has to stick with what they submitted.
Q I agree with that.
A So is that -- am I on track with answering your question?
Q You absolutely are. So the short version of that is the two companies that you're describing can develop different methods for achieving the same compliance with the same regulation, develop -- or producing the same product?
A Yes, provided they submit them, validated and stick with them once they're approved.
Q Understood.
A Yes, sir.
Q And the standards that -- or I'm sorry.

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The procedures that they develop, those can change over time?
A They --
Q They can change over time, correct?
A Not without approval.
Q But with approval they can change.
A With approval after the fact. There's a system of doing it.
Q Well, and let me make sure that we're talking about the same thing.
A Yes.
Q Are you talking about approval with respect only to analytical methods or are you talking about all practices and procedures a company utilizes to manufacture a product?
A Everything from raw materials received to finished goods going out.
Q Everything must be submitted and approved by the FDA before any changes are made?
A If you have a procedure that's been approved and you want to use another procedure -- it might be faster, more accurate, you think -- you have to --
Q Let me --
A Go ahead.

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Q I want to make sure that we're talking about the same thing. So I apologize.
A Okay.
Q But I get the sense that you're using procedure and when you use terms like faster and more accurate, you're using chemistry terms. You're still kind of limiting your answer to an analytical method type context.
A No, I'm not.
Q Okay.
A No.
Q If a company has a procedure for handling documents, who they go to, how they're routed, whether they're kept in secure storage, who has access to that, an SOP that speaks to those issues, is that something that has to be submitted to the FDA before it's changed?
A For handling documents?
Q Yes.
A Record storage?
Q It might not --
A We're not talking about stability testing --
Q No, no.
A -- storage, data that's important for safety?

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Q I'm just talking about --
A Record storage?
Q -- record storage, for example, batch records storage.
A You could --
Q Let's go through this. Batch record storage. When you produce a product you create a record reflecting that production process that's commonly referred to as batch record, correct?
A Yes.
Q And then documents that comprise a batch record vary from one company to the next.
A Yes.
Q The batch records are kept by companies as they manufacture products.
A Yes.
Q They're stored somewhere, I assume.
A Yes.
Q The methods for storing those batch records, who has access to them, how they're stored, whether they're stored electronically or in hard copy, whether they're kept in a locked room, not kept in a locked room, those methods are typically set forth in an SOP, correct?
A Yes.

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Q And SOP means standard operating procedure.
A Correct.
Q You don't have to submit an SOP for that to the FDA before you modify it, do you?
A You do not.
Q Okay. So there are procedures that don't necessarily have to be submitted to the FDA that a company can change over time as it develops a better way to do things or just decides it wants to do something differently?
A The example you gave, correct.
Q There are other examples, right?
A There are probably others, uh-huh.
Q Probably a lot more.
A Yes.
Q Okay.
A Everything I was talking about was in direct manufacturing and testing line that would affect the quality of a product.
Q So you're talking about changing what people in the industry typically refer to as the method?
A Not just the test method. It could be a mixing procedure.
Q Okay.

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A If someone got a new mixer and said, I think I can mix for 30 minutes instead of 45, they would have to run batches simultaneously, tell the FDA and submit analytical data. They couldn't just say this is better, we think it's the same and use it. That would be a violation.

Q And that starts all the way back at the submission of, if you're a generic manufacturer, the NDA -- the -- I'm sorry -- the ANDA --

A The ANDA.

Q -- the Abbreviated New Drug Application.

A Yes.

Q The specific methods, not just analytical methods, but the techniques that a company is going to use to manufacture that product, have to be set forth and then submitted to and approved by the FDA.

A Yes.

Q And so going forward from there, any changes to those techniques have to be submitted to and approved by the FDA.

A Yes.

Q But there are any number of SOPs that are relevant to a pharmaceutical company's operations that are mandated by Good Manufacturing Practices regulations that a company can change without submitting it to the

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FDA.

A Yes. I would say in the case that you just gave, record storage as opposed to data acquisition, data acquisition where you're getting data relevant to the identity, strength, quality and purity of the compound, that has to be approved. But record storage, that would not have to be.

Q Okay. If a company doesn't comply with the procedures that are in place to manufacture a drug, does that mean that drug is adulterated?

A If the company doesn't comply with the procedures? I believe that's defined in the Act as the definition. If a drug is not manufactured in accordance with Good Manufacturing Practices it is considered adulterated. I believe the section is 501 or 502.

Q Okay.

A But, yes. My answer is yes.

Q Okay. So the definition of adulterated in the Act, the Food, Drug and Cosmetic Act, is focused on non-compliance with the procedures that are in place to manufacture that product.

MR. MILLER: Object to form.

A Yes. It's very broad, very broad. If you don't manufacture it according to GMPs it's adulterated.

Q Well, and I want to make sure that what

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you just said is clear in the record. When you say if you don't manufacture it in accordance to GMPs, you mean if you don't comply with the GMPs while you're manufacturing it then it's adulterated.

A While you're manufacturing it.

Q Or if you don't comply with the GMPs either while you're manufacturing it or in some aspect of the production then the drug is adulterated.

A Yes.

Q Adulterated doesn't mean defective.

MR. MILLER: Object to form.

A Adulterated means it's not, to use FDA's terms, of the identity, strength, quality and purity that you purport -- they like that term -- purport to have and therefore, my words, you can't trust it to be of the quality it's supposed to be.

Q Well, adulterated actually doesn't mean it's not of the identity, strength, quality and purity. It means it wasn't manufactured according to the processes in place to try to make sure it meets the identity, quality, strength and purity. Isn't that right?

MR. MILLER: Object to form, misstates his previous testimony.

A Yes.

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Q Okay. So adulterated doesn't actually mean the drug doesn't meet the identity, strength, quality and purity it is supposed to have, correct?

MR. MILLER: Objection, asked and answered.

A It means it can't be guaranteed to have that. So are we saying the same thing?

Q No, because I'm not sure that you're -- you can have a drug that's adulterated and -- well, let's use an example.

If, if I have -- if I failed to comply with a procedure in the course of manufacturing a drug that relates to filling out a form or a part of the batch record, if I have an SOP that says the batch record is supposed to be filled out a certain way and I don't fill out the batch record correctly, is that a violation of GMPs?

A Technically, yes. Could I ask you to be more specific in that case? And I have a reason for asking that.

Q Well, what's your reason?

A My reason is I saw -- it's a good example of what we're discussing. I saw a case where the analyst put the initials and the reviewed by were the same initials. And you're not permitted to review your

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own work. It has to be someone else.
So that's a violation. And technically that material was not produced in accordance with GMPs, because you had -- let's say a guy. It could be a guy or gal, those initials. A guy writes his initials there and then he reviews his own work. And that's against regulations.
Q Okay. So that --
A That's what I was thinking of when you --
Q And let's use that example. That product technically is adulterated.
A Because it was not produced in accordance with GMPs, yes.
Q It doesn't mean it is defective.
A It doesn't guarantee it's defective, but it leads you to question, you didn't make it the way you said you did, why didn't you make it right.
Q But the bottom line is that that product, the fact that it's adulterated for the reason you described does not mean the product is defective.
MR. MILLER: Object to form.
A If I interpret that is there a possibility that the product may still be good, then I agree with you.
Q Well, it's more than just a possibility,

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right? I mean, in that case -- what I'm trying to establish, Mr. Farley, is you've got a circumstance that you described where if you apply a literal reading of the regulations that product is adulterated.
A Yeah.
Q To determine whether the product is defective you'd have to actually test the product, right?
A Yes.
Q So to determine whether the product is -- was actually manufactured within the specifications for the product, you'd have to test it.
A To determine if it was actually manufactured within the --
Q Yes, whether it actually has --
A Whether it is what it's supposed to be?
Q Yes. You have to test it.
A Yes.
Q So the fact that it's adulterated doesn't tell you whether it's within specification.
A It does not tell me it's within specifications, but I -- if a firm said to me, look at this contract manufacturer, and I went to the contract manufacturer that my client firm wanted me to give an opinion on and I saw that, why are you doing this? Why?

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I mean, how do I know to trust you with anything else you're doing? You're fouling up here. And my recommendation would be to the pharmaceutical firm, don't deal with them, because --
Q You've really --
A -- it leads you to wonder.
Q Because one -- non-conformance with one practice or procedure you'd recommend not dealing with them at all?
A I recommend not dealing with them until they found out why and what the reason was for it and I would -- I've done it. I've said to a firm, I would seriously consider not dealing with Contract Manufacturer A and here's the reason, it's in my report.
Q Well, and don't -- let's take it out of the context of a company potentially dealing with a contract manufacturer.
A Okay.
Q Let's just deal with a company that's manufacturing products.
A Everything in-house.
Q Right. So if a product is adulterated -- we've already established that doesn't mean it's defective -- it doesn't say anything about whether it's safe or unsafe either, does it?

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MR. MILLER: Object to form.
A It doesn't say definitely that's it's safe or unsafe.
Q It doesn't say anything about whether it's safe. You'd have to test the product to make that determination.
A Yes.
Q I'd like to talk a little bit about some of the things in your article. If you'd pick up Exhibit 46, please.
A I have it.
Q Give me one second. This is what happens when you leave your highlighted copies. You said a moment ago that the procedures a company is going to use to develop its -- or to produce its drugs are submitted to and approved by the FDA; is that correct?
A Yes.
MR. ANDERTON: Let's take a couple of minute break. We're about -- we're about there, aren't we?
THE VIDEOGRAPHER: Yes, sir.
MR. ANDERTON: Okay. Let's take a couple of minutes and then I can get a little more organized on this.
THE VIDEOGRAPHER: We're off the record

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at 11:11.
(A brief recess was taken.)
THE VIDEOGRAPHER: It's 11:20 a.m. We're back on record and this is the beginning of Tape No. 3 in the deposition of James J. Farley.
BY MR. ANDERTON:
Q Mr. Farley, if you will pick up the article, your -- the article that you co-authored and look at the first page. It's -- and I'm talking about Exhibit 46.
You see the bottom, the very bottom of page 1 and continuing on to page 2, the last sentence of that last paragraph on page 1 reads, The FDA's acceptance of submitted procedures is evidence, not conclusive proof, of the reasonableness of the company's manufacturing practices and procedures, and the trier of fact may assign FDA approval the weight it deserves.
Did I read that correctly?
A Yes, you did.
Q Do you agree with that statement?
A I'm going to read it one more time.
Q Take your time.
A Of course, I've known Gene since we moved down here five years ago and I would be reluctant. But I'm going to do just like you said.

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Q Well, let me ask you first, is that something you drafted or Mr. --
A Gene Brooks.
Q -- Brooks drafted?
MR. MILLER: Give him a chance to read it.
MR. ANDERTON: I am. I am.
Q Take your time. Why don't you go ahead and review it as you need to.
A When you get into terms like trier of fact, that's Gene. And -- but he -- sometimes we just meet for lunch. Other times he'd send me an e-mail. And we look and he says, this is my statement, and I say, well, yeah. The FDA's minimum standards you have to at least do this. That's the way I would have wrote that.
Q Okay. So it's minimum standards?
A Yes.
Q If you comply with the submitted procedures, as the term used here, you submit procedures and get them approved by the FDA. If you comply with those, have you achieved compliance with Good Manufacturing Practices?
A If you comply with every procedure -- and I'm going to use my terminology again of raw materials

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received to finished product. If you comply with all of them there are cases where companies comply in one area and they in fact foul up or are violative in another. That ruins the whole -- right on down the line everything has to be in compliance. Then, yes.
Q Well -- okay. But I guess I want to make sure that you answered my question, Mr. Farley.
A Okay.
Q If you comply with the submitted procedures, have you achieved GMP compliance?
MR. MILLER: Objection, asked and answered. It's okay to answer.
A If you comply with every one of the submitted procedures that had been approved relevant to the manufacturer of a given product then --
Q Have you achieved GMP compliance?
A Yes.
Q And you believe that a jury could still hold the manufacturer liable and award damages if somebody achieved that compliance that you've just described?
MR. MILLER: Objection, misstates facts in evidence and previous testimony.
A I don't know what goes on in jury's minds. I don't know how I can answer that.

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Q Okay. So you can't -- I guess that means you really can't speak to whether that sentence that I read regarding whether a trier of fact -- or regarding a trier of fact assigning its own weight, you can't agree or disagree with that?
MR. MILLER: Object to form.
A Well, I will agree with anything that I wrote here. But your question was what I thought would go on in a jury's mind and I have no idea what goes on in a jury's mind.
Q But you -- so then you agree with what's written here?
A I wrote it. I have to. Definitely.
Q Okay. So you think a jury can take a company that's achieved GMP compliance and still hold it liable?
MR. MILLER: Object to form, misstates the testimony.
A I'm not getting the connection of -- it sounds like you're changing subjects on me.
Q No. I'm talking about this sentence. If you agree with it then you think that a jury can take a company that is complying with Good Manufacturing Practices and say, not good enough, we're going to hold you liable.

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MR. MILLER: Object to form. That's not what it says.
A I'm not deliberately trying to be evasive. I just -- I'm not getting it. I'm not --
Q Do you agree with what I just asked?
MR. MILLER: Object to form.
A I'm still going to ask you one more time.
MR. ANDERTON: Can you read that back, please?
(The record was read back as requested.)
MR. MILLER: Mike, that's not what the statement says.
A If the company complied with Good Manufacturing Practices on every approved -- FDA approved procedure from raw materials in to finished product out --
Q Yeah.
A -- and didn't turn the other way for any other situation, like if a carton was broken putting on a truck and they look the other way and said, forget it, we're done, if they did that then they've done everything in accordance with FDA regulations.
Q Can a jury hold them liable for damages in that context if a consumer takes their product and is injured?

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MR. MILLER: Object to form.
A I can't predict what a jury would do. That's what I'm having trouble with.
Q I'm not asking you to predict what they will do. Are they permitted to do that?
MR. MILLER: Object to form.
A A jury is permitted to do whatever the judge tells them within the range.
Q And you think it's appropriate that a company that achieves that absolute compliance that you just described can be held accountable -- or can be held liable for damages?
MR. MILLER: Object to form. Mike, you're misstating -- you're asking questions about a statement that don't compare.
Q Okay. I'm asking a question that I think flows directly from this sentence, so --
A I'm pausing because I haven't seen a company that has been in complete compliance ever get in a situation like that. When you're in compliance you don't get involved in that thing.
Q So if you're in compliance you never get sued?
A I can't say never get sued. I say that in my eyes if you're in compliance you are quite likely

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making a quality product.
Q That doesn't mean you can't get sued.
MR. MILLER: Object to form.
A No. You can get sued any time for anything. Whether it goes through or who decides what, that's another story.
Q If a consulting -- a prospective consulting client -- well, let's not call it prospective.
If you are hired by a pharmaceutical company to consult as to how to avoid litigation -- have you ever been hired to do that?
A Specifically help me to avoid litigation?
Q Yes.
A No, not in those words, no.
Q Okay. If a company hired you as a consultant to advise it how to achieve regulatory compliance -- well, if a company -- let's -- I'm going to not ask that question. I'm going to start a brand new question. Okay?
If a company hired you and said, Mr. Farley, we'd like you to tell us how to manufacture and produce any product, it doesn't matter what the product is, and we want to do it so that we minimize or eliminate the possibility of getting sued by consumers, what would you

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tell them?
MR. MILLER: Object to form of the question.
Q What would your approach to that engagement be?
A Word for word the way you just presented it, I'd say, well, as far as getting sued, I don't have anything to do with that. Anybody can sue you any time. You want to get in compliance, I'll talk to you about getting in compliance.
As far as litigation, you talk to your attorneys about that. I will help you get in compliance and then I would go through the procedures as how -- I would be asking them records of their previous inspections, their previous internal audits.
But I wouldn't answer it the way it was phrased, because I can't tell whether you're going to get sued or not. I will say, I can give you -- I will make you be in compliance -- I will help you be in compliance, I'll show you how to do it. And it would -- that would be it.
Q And would you do that because if they were in compliance they, as you said a few moments ago, they don't find -- they wouldn't find themselves in that situation or they'd be less likely to find themselves in

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that situation?
A I would relate the more you are in compliance the less possibility of litigation coming about or a lawsuit being filed against you. I would believe there's a relationship there.
Q Okay. Go to page 3 of this article, please.
A Okay. I'm on 3.
Q And I want to -- first I want to ask you about the headings. You've got -- on the first heading -- actually there are no headings until you get to page 3. But then you start having headings, Prefiling Investigations, Discovery, Standard Operating Procedures, Documentation of Internal Plant Construction, FDA Inspection Documents.
Do you see those headings?
A Yes.
Q You know, the title of this article, Mr. Farley, is "Discovering the Cause of a Drug's Defect". It reads more to me like a how to manual on how to sue pharmaceutical companies.
Am I mischaracterizing it by reading it like that?
MR. MILLER: Object to form.
A I think that a person could interpret it

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like that, but that was not my intent. Gene and I thought, let's put our heads together and let's write an article. Gene never expressed to me that it was his direct intent.
We just thought it would be nice to work together on an article and get it out into the industry. And I thought it would be nice to work on something that would appear in a law journal.
Q Didn't care what the subject was or what impression it might have?
MR. MILLER: Object to form.
A Didn't care. That's a question mark, didn't care. There are certain ones I probably wouldn't write, either not knowledgeable or just didn't care to talk about. But since it sounded like a good subject, product liability, and we both had an interest in it, we put our minds together and wrote it.
But it was not my intention and I believe, knowing Gene and Jim the way I do, that -- and I'm guessing here -- that it's not their intention to how to sue manual.
Q Well, knowing what you do, what -- do they handle cases where consumers sue pharmaceutical companies?
A I don't know anything about Gene's cases.

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Q Nothing?
A Nothing.
Q You don't know anything about his cases?
A I've never done work for Gene. He's referred me to other attorneys, one in particular in town for whom I did some work. But I have not worked for him directly.
It's more of a -- I don't know if I should use the word social, but just -- he was someone I met when we first moved to Savannah and he clued me in on different things in Savannah and we hit it off more as friends.
Q Okay. Turn to page 3 of your article, please.
A I'm there.
Q Do you see the paragraph under the Prefiling Investigation heading, the third paragraph on page 3?
A It starts with the word Microbiological?
Q No. Do I have a different copy than you?
A I'll show you mine. That's what I've got.
Q Third paragraph. I'm sorry. Not -- the third paragraph on the page. I didn't say that clearly. My apologies.
A It begins with, When a client?

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Q That's the one.
A I'm there.
Q It reads, When a client comes to you suspecting that he or she has taken an adulterated drug, you should tell the client to save the drug, the container and all labeling and packaging information. A laboratory must analyze the drug and test for its active pharmaceutical ingredient, paren, API, closed paren, and for strength and purity.
Did I read those two sentences correctly?
A Yes, you did.
Q So if you think a drug is adulterated you have to test it to determine whether it was defective. We established that earlier, right?
A Yes.
MR. MILLER: Object to form, misstates previous testimony.
Q Well, that's what this says, right?
A Well, what -- to put that in perspective, I remember we were talking about it and Gene said to me, what's the first thing you do? I said, if someone took a drug and had some sort of adverse event, adverse effect, and they thought something was wrong with it, if you are going to represent them or anyone who wants to learn more about the situation, either side, so to

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speak, your best bet is that container, the remainder of the material in it, and get data right there as opposed to comparing it to something that was made at some other time.

Q Okay.

A So that's what we were talking about here. Your best bet is do you have the same container of medication and what's the lot number. And you can be more specific in getting to the solution of the problem.

Q And ultimately what you're describing is a method to determine whether the product was defective.

A Yes, for either side.

Q Understood. And you should make that determination whether the product is defective before you file a lawsuit, shouldn't you?

MR. MILLER: Object to form of the question.

A That's for an attorney to judge, but I would think so. But I don't feel that -- I feel attorneys are better qualified for that because they represent their clients.

Q Okay. Can you sue a pharmaceutical company just because you take a product that's adulterated?

MR. MILLER: Object to form of the

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question.

A You being an individual?

Q A consumer, yes.

A Can you sue a pharmaceutical company just because you took a product that's adulterated? That's between you and your attorney.

Q You don't know?

A Well, I know that anybody can sue anybody over anything any time in the U.S. today.

Q Well, you also know --

A So that would be yes.

Q Well, but is adulterated -- well --

A I think, if I can interject something --

MR. MILLER: Hold off. There's no question. When he asks a question you can answer.

Q Yeah, Mr. Farley, I appreciate that and I --

A I'm holding off.

Q Okay. Look at the heading on -- still on page 3 that says Discovery. Do you see that heading?

A Yes.

Q It's important to request and review documents when you're considering whether you should -- whether you can and should sue -- well, take that back.

It's important to request and review documents

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if you're trying to figure out whether you've got a claim against a pharmaceutical company, correct?

A Yes.

Q And that includes reviewing batch records.

A Reviewing --

Q Batch records.

A Batch records, yes.

Q I mean, you say in the article here that you should start by requesting a review of the batch records; is that right?

A Of that particular lot of the bottle in question, or container in question.

Q If you can do that you should -- that should be the first place you look is you look at batch records of that particular lot.

A Yes.

Q And that will tell you whether the product was manufactured in compliance with Good Manufacturing Practices.

MR. MILLER: Object to form of the question.

A Yes. It's the first place to look. Deal with the specific product that seems to be causing their problem.

Q I understand. And like I said, that will

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tell you whether the product was manufactured in compliance with Good Manufacturing Practices.

MR. MILLER: Object to form of the question.

A If everything on it is presented accurately and honestly, yes.

Q Okay. Your expert opinion in this case doesn't speak to the accuracy of Actavis' documents, correct?

A Doesn't speak to the accuracy of Actavis' documents?

Q Yeah. You don't offer an opinion about whether the documents -- whether Actavis' records are accurate.

MR. MILLER: Object to form of the question.

A Specifically -- I noticed something in that double initial where the analyst was also the reviewer, which I noticed that. I also in another document that I could find upon a short search where I saw an analysis of an impurity.

And those results jumped out at me like they are so precise, I mean, abnormally precise, more precise than most people would see, which leads you to wonder did they really run it. But that's speculation, of

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course. But that would -- so if everything was correct then the product should be good. But --
Q But I want to make --
A What was your original question?
Q My question is, you're not offering an opinion in this case about whether Actavis' documents are accurate, are you?
A I have questions about some of the things on them, but the way you worded the question, I am not questioning. I'm not believing they all are accurate, but I'm not questioning them.
Q There's nothing in your report expressing any opinion that the information in Actavis' documents is inaccurate, right?
MR. MILLER: Object to the form of the question.
A There is an opinion in one file where they did an impurity determination and they got -- I believe it was 1.61 percent and 1.61 percent. And I said these are fantastically precise results.
And I questioned the accuracy, one might even say the legitimacy of that. I would like to see the analyst's records on that. I don't have them. I would like to see them.
Q When you say in one file, you're not

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talking about your report?
A In one of the documents I reviewed, one of the 93 documents.
Q So if I understand correctly, in one of the 93 documents you reviewed you saw one test result for impurity that in your mind caused you to question some aspect of the performance of that test.
A No, no. In one I saw a set of results that led me to question that. There were a series of analysis. It wasn't just one. One would not cause me to question it, but a series did. And in another I saw the analyst and reviewer having the same initials.
Q There's no mention of either of those things in your expert report.
A Not in the report. It's in the files I reviewed, the individual files.
Q I understand. So you're talking about information in documents that you reviewed --
A Yes.
Q -- not in your expert report which contains your expert opinions, right?
A Yes.
Q You understand --
A Yes, you're correct it's not mentioned in the report specifically.

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Q And you understand, Mr. Farley, that you've been retained as an expert witness in this litigation to give an expert opinion on certain subjects.
A Yes.
Q The accuracy of Actavis' documents is not one of those subjects; is that correct?
A It is not one of them. Some things raise eyebrows, but I did not have enough data to make a conclusive decision. Did that answer it? I know it might be answered, but I'm trying to put it in the proper perspective for you, for all of us.
Q It's your answer. The FDA when it conducts inspections and based on your experience, if they thought a company had fraudulent or falsified documents, they'd take very swift and very decisive action, wouldn't they?
A I would hope so. And I've known them to do it in those cases.
Q Okay. And what actions would they take?
A They immediately do a review of all relevant documents to look for the extent of it and the backgrounds of the individuals involved.
Q What action would they take with respect to that company's continued participation in the market,

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leaving their products in the market?
A Until they were sure they would be doing the investigation. It's like any time. You're doing the investigation but you -- it depends on the potential result out here as to whether you shut them down now or have a potential for shutting them down later. They would do the investigation, depending on where they thought the fraud was.
Q You reviewed a series of FDA documents --
A Yes.
Q -- relating to Actavis, correct?
A Correct.
Q No reference to even the possibility of fraud in any of those documents, is there?
A Correct.
Q So the FDA didn't think Actavis' documents were fraudulent.
A Correct.
Q When you're -- let's go back to documents. If you're looking at -- I'm sorry. Let's go back to your article and specifically your review of batch records.
If you're looking to -- and if you look at the -- your discussion of batch records here, it goes on for almost a page. And if you look at the second

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paragraph on page 4 it starts -- well, no, the first full paragraph, Batch records contain a wealth of information about the production history of a specific drug.

These records contain the names of people actively involved in the manufacturing process, operating procedures followed -- and there's a parenthetical -- relevant dates and times and, most important, the results of sample tests.

Essentially what you're saying in this article is you're looking for evidence of GMP violations.

A I'm looking to see how it was manufactured. If I was looking for a violation that's where I would look for a violation. If I was looking to see that they made it correctly that's where I would look to see that they made it correctly.

I guess my answer is it depends what side you're on and what you're predisposed for looking. But that's going to give you the answer.

Q Objectively if you're looking for those through batch records -- and I guess if you're on the plaintiff's side you're looking for evidence of GMP violations when you review the batch records.

A Yes. Of course, the firm itself does -- should do periodic reviews to ensure that everything is

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correct. That's why I'm saying both sides. When firms do their own audits, which they should do periodically, they would review batch records, not looking expecting something is wrong, but expecting everything to be correct.

Now, a plaintiff's representative, on the other hand, might review it looking for that. So that's why I'm saying, you can review it either way depending on what you're looking for.

Q You're looking for different things, but neither side can determine -- let's ask a slightly different question.

You can't determine if there were GMP violations associated with manufacturing a product without reviewing the batch records, correct?

A There are cases where you could. There are cases where it would be obvious. You look at the product and you see a crack or a double size. I mean, double size, I don't need to look at a batch record to -- I want to look at the batch record after the fact, but I can see there's something wrong here.

Q Assuming you're not holding product that is obviously -- well, let's explore that concept. Let's assume you're looking at a double thick tablet. It doesn't mean it was -- GMPs were violated when it was

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manufactured, does it?

A If you're looking at a product, just the product, that's it.

Q Yeah.

A You have the product in your hand.

Q Yeah. It's twice the size it should be. That could happen even if you have absolute strict compliance with all relevant Good Manufacturing Practices in the production of that product, correct?

A Provided it didn't get to the consumer. You're talking about the employees.

Q If it gets to the consumer that doesn't change whether it was manufactured properly.

A What does matter is what did you do about it. Did you --

Q Mr. Farley --

A -- do an investigation --

MR. MILLER: Let him answer the question.

Q -- answer my question. If I have a defective tablet in my hands --

A Defective, your word.

Q Okay. It's twice as thick as it should be.

A Yes.

Q It doesn't mean any GMPs were violated in

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manufacturing that product, does it?

MR. MILLER: And continue with your answer when you were cut off, please.

A It means something is wrong somewhere. This is not the product we want. Let's launch a Corrective Action/Preventive Action investigation into it. And then that would have to be launched the proper way to investigate it.

It means something went wrong somewhere. And at that point you don't know where or why, but you have to investigate it. Failure to investigate it would be a GMP infraction.

Q Okay. But you still haven't answered my question.

A Okay.

Q It doesn't mean --

A One more time.

Q -- anything -- any GMP was violated while it was being manufactured.

A Yes, it does.

Q What --

A Because it's supposed to be a certain weight and a certain size.

Q Okay. But --

A And it's not.

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Q How could you know what GMP was violated just because it's out of specification? You can -- is it true or not you can comply with every single GMP requirement associated with manufacturing a product and still produce a product that happens to be out of specification?
A Theoretically you're not complying. Something went wrong somewhere.
Q Something went wrong doesn't mean you didn't comply with Good Manufacturing Practices.
A The system that you're trusting didn't comply --
Q That doesn't mean --
A -- that you --
Q That means something went wrong. That doesn't mean you didn't comply with Good Manufacturing Practices, does it?
A You try to comply. You didn't make a double thick tablet deliberately. But once you saw it was double thick you know here's the specifications for thickness and for weight, this is too thick and it weighs too much, something is wrong with the system, let's investigate it.
It's a defective product as you yourself said. And what are we going to do about it? What are you

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going to do about it now? That's --
Q You're talking -- but now you're talking about after the fact. And I agree. If you have a defective product and you learn of it, perhaps from a consumer, perhaps it comes back from a pharmacist, I agree that now you have to determine what you're going to do about it.
But you're not answering my questions about the processes that resulted in production of that product. You can comply -- is it true or not, you can comply with every single Good Manufacturing Practice associated with manufacturing a product and it is still possible that you could produce a product that is not within specifications?
MR. MILLER: Objection, asked and answered.
A Here's -- I'm going to reword a certain way, because I can't answer that yes or no. I'm going to say you can believe you complied with everything according to the way your high moral character, your high ethics and the way you set your system up.
But you've got the evidence sitting right there in the palm of your hand something is wrong somewhere. I obviously didn't comply. Why didn't I and how can I fix it?

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Q You -- it's not that you didn't comply. It's that you -- the process didn't work properly. That doesn't mean you didn't comply, does it?
A The process didn't produce the material within specifications; therefore you didn't comply.
Q That's not true.
A You didn't mean not to comply, but you didn't comply.
Q You didn't produce a product that was within your specifications. That does not -- do you believe that automatically means you didn't comply with the procedures you were supposed to?
A Yes, I do. And what comes to mind is did Prius comply with the accelerator pedal? Is BP complying with the oil in the Gulf? I mean, you know, something is wrong somewhere, because the cars are going there, your oil is going out in the Gulf.
You've got a tablet in your hand that you acknowledge is defective. You didn't mean not to comply, but you didn't comply, because if you did you would have had a quality product that met specifications. You wouldn't have that double thick tablet in your hand.
Q The Good Manufacturing Practices regulations require that you develop a procedure for

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every step in the process of manufacturing a product, correct?
A Yes.
Q And they require that you submit those to the FDA --
A Yes.
Q -- and get approval, right?
A Yes.
Q And then they require that you follow those procedures, right?
A Yes.
Q If you do that, develop them, submit them, follow them, have you achieved compliance with Good Manufacturing Practices?
A If you look at your final product and it meets all the specifications assigned to that product and approved by the FDA, then you have. If it does not meet those specification then you have, by your definition, a defective product and you didn't comply even though you thought you did and you meant to.
Q How does that speak to whether you complied? Because your product had a defect in it -- the regulations don't require perfection, do they?
A They require that the product be within the defined and approved specifications. That's not

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perfection. It doesn't need perfection. But you have to make it the way you say you'd make it.
Q If you're counseling one of your -- well, let's back up. You've been consulting and giving counsel to pharmaceutical manufacturers for 13, 14 years since you left the FDA?
A Fourteen.
Q Okay. You've been involved in circumstances where they conduct investigations into out of specification results?
A Yes.
Q You don't always find a root cause, do you?
A No, once in a while you don't. But you have to exert a certain amount of effort to look into it.
Q You have to try.
A Uh-huh, yes.
Q But it's certainly possible and it happens that you can do a completely thorough investigation into the circumstances you're involved with and not determine the root cause for why that happened.
MR. MILLER: Objection, asked and answered.
A It is possible and it happens once in a

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while.
Q Okay. And the industry as a whole is based on sampling protocols, right?
A The industry is based on sampling -- the industry uses sampling protocols.
Q Well, and --
A Or is --
Q Maybe we're saying the same thing.
A I'm not questioning your choice of words, but maybe reword it.
Q Well, maybe we're saying the same thing. The release decision was used -- or the release decision made by all companies in the industry are -- they use sampling protocols to make those release decisions.
A Take your samples of whatever you're sampling for analysis to get your data.
Q You don't test every --
A Not a hundred percent.
Q -- individual tablet or -- and let's stick with tablets. You don't test every tablet for compliance with all specifications.
A Correct.
Q And does any company test every tablet?
A You wouldn't have anything left to sell.
Q Not very economically viable.

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A Not economically viable.
Q So the industry is based on sampling protocols.
A Correct.
Q Deviations during a -- you talk in your article about, the top of page 5, Corrective Action and Preventive Action. And you advise in the article that you should request CAPA, C-A-P-A, records for the time period that includes the production of the questionable lot. If something happened during production that differed from approved procedures, this will be noted as a deviation, which the company must investigate.
Did I read that correctly?
A Yes.
Q Deviations can occur during the manufacture of a batch and a batch can still be released properly, correct?
A If the deviation was investigated according to your protocols or procedures and found to be acceptable, it can occur.
Q Okay. And you counsel manufacturing -- companies that manufacture pharmaceuticals. You run into, I would assume fairly regularly, deviations that are properly investigated and the batch is still released.

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A Fairly regularly, yes, uh-huh. That's right.
Q So there's nothing -- well, strike that.
Going back to reviewing batch records, batch records will show whether a product was tested properly in the lab, correct?
A It will show theoretically everything in the production line including --
Q So you need to answer my question now, Mr. Farley.
A Yes.
Q It will show whether a product was tested properly in the lab.
A Yes.
Q It will show whether the results of that laboratory testing were within specifications.
A Yes.
Q If the FDA was conducting an inspection of a facility and wanted to determine whether the company had complied with Good Manufacturing Practices, it would review batch records, right?
A Yes.
Q And from that review would make a determination about whether the FDA believed, whether the inspector believed there was some non-conformance.

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A Yes.
MR. MILLER: Object to form.
Q And let me make that -- some non-compliance with Good Manufacturing Practices.
A That would be one of the things. They would have a whole schedule of things to look at of which batch record examination would be one.
Q When the FDA is -- well, never mind. I'll ask that later. You can also review SOPs to determine whether a company has complied with Good Manufacturing Practices.
MR. MILLER: Object to form.
A You look, A, for existence of the proper SOPs; and B, for the fact that they're using them and doing what they say.
Q Right. So there are two -- there's actually two forms of GMP compliance associated with SOPs. First, whether the SOP itself satisfies the minimum requirements of the regulation, right?
A Yes.
Q When it's drafted properly.
A Yes.
Q And second, whether you comply with the SOP during your manufacturing process.
A Yes.

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Q And again, the FDA when it is inspecting a company for GMP compliance it might undertake both of those reviews.
A Yes.
Q It might review the substance of the SOP to determine whether it believes it meets the minimum requirements and it also might review the batch records to determine whether you actually have complied with the SOP during manufacturing.
A Yes.
Q You can't -- you can't determine whether you've complied with the SOP without reviewing the batch records.
A In the case you're talking about, correct.
Q Well, is there any case where you could determine compliance with an SOP without reviewing the batch records?
A They would be SOPs not relating to the batch, like the example you gave earlier.
Q Okay. Related -- well --
A I can't qualify my answer.
Q -- you can't determine -- and I apologize for talking over you.
A That's okay.
Q You can't determine whether you've

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complied with an SOP that relates to the manufacture of a specific product without reviewing the batch records.
A That's your most sure way, yes.
Q Okay. If you were doing a consulting assignment that's what you could do?
A Definitely.
Q You wouldn't tell that company whether they complied or not without reviewing the batch records. That's being thorough like you described earlier.
A Correct.
Q How would you offer an opinion about GMP compliance with respect to manufacturing a specific product without reviewing batch records?
A How would I offer an opinion about --
Q Yeah.
A -- compliance?
Q You couldn't -- well, you couldn't offer -- you, Mr. Farley, as a consultant you couldn't offer an opinion about whether a company -- if a company came to you and said, I want to know whether we've complied with GMPs as we manufactured and released these batches of this product.
A Sure.
Q You could not undertake that exercise

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without reviewing those batch records, right?
MR. MILLER: Object to form.
A I could not be assured of it without doing the batch records. And I would say in plain everyday terms, I want to see how it's made. And they would say, oh, we'll have the batch record for you right away.
Q And what if they said -- well, you wouldn't offer an opinion about whether they had complied with GMPs in manufacturing and releasing that -- those batches of that product without reviewing the batch records.
MR. MILLER: Object to form.
Q As you said earlier you'd say, I can't do that, I need to turn that down.
MR. MILLER: Object to form, misstates previous testimony, incomplete hypothetical.
A Could you give me the question again?
MR. ANDERTON: Could you read that back, please?
(The record was read back as requested.)
A I would have to review the batch records to render a complete opinion as to whether everything was done properly. Is that -- am I answering -- sure.
Q Okay. Go to the heading in your article Witnesses, page 6.

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A I have it.
Q Take a look at the fourth full paragraph under that heading. It starts, When discussing. Do you see that?
A I'm with you.
Q And it reads, When discussing alleged violations the expert should be able to describe what should have been done and why and the difference that compliance with relevant GMPs would have made to the finished product.
He or she must connect the specific GMP violation to the negligence or defect that caused injury or loss. This causation connection is important as determining the GMP violations -- I'm sorry -- this causation connection is as important as determining the GMP violations because irrelevant GMP violations cannot establish the prima facie case.
Did I read that correctly with that little glitch in there where I went back and started that last sentence over?
A You read that correctly.
Q Okay. So you've got to have an expert witness identify specific GMP violations and they have to apparently -- well, you believe that they have to actually connect directly to a specific defect, correct?

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MR. MILLER: Object to form.
A In order to correct it, yes.
Q Well, this isn't talking about correcting it, Mr. Farley. This article is about whether you can bring a lawsuit against one of these companies; and if so, how to do it, right?
A Right.
Q Okay. So the paragraph I read where you say -- where it reads, The expert must connect a specific GMP violation to the negligence or defect that caused injury or loss, you agree with that, right?
A Yes, I do.
Q And you also agree that irrelevant GMP violations -- and by irrelevant that means a GMP violation that doesn't actually relate to the defect that allegedly caused harm to a consumer, correct?
MR. MILLER: Object to form.
Q Is that what that means?
A It doesn't mean not important. It means not relevant to this situation.
Q Right. So you could have a GMP violation that doesn't speak to the -- or in any way relate to the defect that caused a consumer harm. That's what you mean when you use the term irrelevant GMP violations.
MR. MILLER: Object to form.

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A Yes. I had to hinge a bit when Gene, Jim and I were writing that about using that term, but we talked about it like we're talking now. It doesn't mean not important. It means not relevant to that path.
Q Okay. What GMP violations can you connect specifically to Digitek?
MR. MILLER: And you feel free to pull out the documents and go through them a page at a time if you like.
A Pretty much the -- all the 483s that were written. They mention one case. I'd have to get the 483s to bring them out.
Q We're going to get to those.
A Okay. And they're -- now, they are printed.
Q I've got plenty of copies. Don't you worry about that.
A I'm sure. I would have guessed that. They're all listed in there. An observation on a 483, an observation of a particular GMP violation, and then there are examples given. It doesn't mean this is everything. Like here's the few examples of this observation which is a violation.
And I believe the inspection that concluded in May of 2008, I think it had 20 observations on it, which

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was really a lot. I mean, that's a lot for a 483. And so their rule -- offhand I'd say they're all GMP violations on that document.
Q Well, we're going to talk about whether you're correct then that a 483 reflects any violations of anything.
A I would modify it slightly perhaps, but I'm sure there's a lot going on.
Q Modify it to what?
A I might say 18 out of 20 or something like that.
Q No. What --
A But right now I'm saying every one on there was a GMP violation.
Q And you said as you started to describe a 483 and what's on a 483 that it lists what the inspector believes is a violation and then examples.
A Yes.
Q Is Digitek listed in all 20 or 18 of those examples on that 2008 483, do you remember?
MR. MILLER: Object to form of the question.
A I believe that not every one refers to Digitek. But to me reading it it relates to the overall system of quality assurance or a weak quality assurance

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program. But in answer to your question, I don't believe every one in there refers to Digitek, per se.
Q Well, if you have an observation on a 483 and you have examples, as a consultant to the pharmaceutical industry, if a company said, we'd like you to audit our records and identify all the products this observation relates to, you'd have to go look at the batch records, wouldn't you?
A I would.
Q So if an observation doesn't refer to Digitek, in order to determine whether that observation relates to Digitek you'd have to look at Digitek batch records.
A In order to determine if it related to Digitek, but I would have formed an opinion as to the overall system or management or the way the company runs. I mean, in plain words I might say this, this thing is all fouled up, I don't know what they can make right. I mean, that's plain terms but --
Q So that might be your initial thought, I don't know what they can make right, but then you'd go to the batch records and determine whether they did make it right.
A Yes, I would.
Q Okay. And if you didn't do that then you

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can't say with any certainty whether the observation relates to any product where you didn't review the batch records, can you?
MR. MILLER: Object to form.
A It would relate to the product that the investigator listed. I would have to believe his or her statement on the 483. But to look at how much of it, I'd have to review.
Q Well, and to determine whether it related to any product that's not listed by the investigator you couldn't do that without reviewing batch records for that product, could you?
MR. MILLER: Object to form. We'd have to take a look at each one individual.
A Yeah. We would have to look at every one.
Q Every one what?
A Every product and all the batch records. I would have an idea as to whether it would or not by looking at that as I did look at the 483. But to be sure you'd have to go through each one of them.
Q And unless you did that you couldn't offer an opinion about whether it actually relates to each product.
A I could offer an opinion. I just wouldn't be sure of it.

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Q Okay. And your opinion in that context without being sure would be speculation.
MR. MILLER: Object to form.
A If you use that term. I wouldn't want to -- I wouldn't want to take any of the firm's products until everything was investigated.
Q Okay. But, Mr. Farley, the answer to my question is, yes, it would be -- until you did that review it would be -- you could offer your opinion but it would be speculation.
MR. MILLER: Object to form.
A Speculation? Yes. Okay. Yes.
MR. ANDERTON: What have we got?
THE VIDEOGRAPHER: Eight minutes.
MR. ANDERTON: Eight? I'm not going to -- we're almost getting about to a breaking point. I'm going to talk to Ericka for a moment. So we're gonna step outside. If you'll just sit tight for a minute. We're within a couple minutes of a break.
THE WITNESS: Sure. Whatever you like.
MR. ANDERTON: But I want to --
THE VIDEOGRAPHER: Off record at 12:14.
(A brief recess was taken.)
THE VIDEOGRAPHER: Okay. We're back on

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record. The time is 1:19 p.m. We did -- this is the beginning of Tape No. 4. We did conclude Tape No. 3 at 12:14 p.m. and we broke for lunch.
BY MR. ANDERTON:
Q Hello, Mr. Farley. Welcome back from lunch.
A Thank you.
Q You understand that you are still under oath?
A Yes.
Q Okay. And I want to just state, as I am admonished for not wearing my microphone, that, implicitly admonished, that while we were off the record you copied over to a portable thumb drive that I have with me all of the documents that were on your thumb drive and that relate to -- the thumb drive that we discussed earlier and that relate to the Digitek litigation and your engagement for Plaintiffs in this litigation. Is that correct?
A Yes, it is, in your presence and Peter Miller's presence.
Q Okay. So it is your understanding that all electronic documents that are on that thumb drive that relate to this litigation have now been placed onto my thumb drive?

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A You are completely up-to-date as of this minute --
Q Okay.
A -- on everything I have.
Q And thank you for that.
A You're welcome.
Q Mr. Farley, what were you asked to do in the context of this engagement?
A Essentially it was, Jim, we want you to evaluate some documents for us and assess the situation, there will be a court case, here's the product, here's the company, I want you to have some documents and render your opinion about this.
Q Render your opinion about what?
A About the status of the situation. These are my words, now. This is not a quote. I don't remember the -- I couldn't be quoted that part back.
But essentially what about this product and that company that makes the product, would you review these documents, give an opinion, at which time I said, well, I'll give you an electronic review of each document and then I'll render an opinion.
Q When you say an opinion about the status of this product, do you mean the regulatory compliance status of that product? What do you mean by that?

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A Did I use the word status?
Q You did.
A I didn't mean to use the word status. About my evaluation of what this product is like and what the company is like.
Q Okay. So your evaluation of what the product is like and what the company is like with respect to what?
A Are they in compliance with FDA regulations.
Q Generally? Is that what you were asked to do, evaluate whether they were in -- whether this company, Actavis, is in compliance with FDA regulations generally?
A Most clients -- some clients will be very specific with you. Others will say generally and as specific as you want or tell me what areas you feel you should put -- you want to talk more about or whatever. It's essentially since I hadn't seen any documents, read these, give an evaluation to whatever depth you feel.
Q Okay.
A Those are my words.
Q I understand. And I need to have as clear as I can understanding with respect to an evaluation of what? I mean, what are you evaluating? What were you

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evaluating as you read and reviewed the documents you were given?
A I was evaluating at a very minimum a product called Digitek and a company called Actavis -- Actavis U.S. I believe it's called -- with regard to how well they can or cannot produce quality material.
Q With respect to Digitek specifically what were you evaluating?
A We looked at that one particular lot where we had the double thickness, but as time went on I looked more into the systems and began to realize that I wouldn't trust anything made by that company. I might have digressed a bit there.
But it was essentially, look it over and tell me what you find. I don't really have clients that -- they don't tell me the answers they want. They tell me to look it over and tell me what you find. And then I say, I'll send you individual reports, individual files of each review.
Q Okay. But you were asked to look specifically at a product, Digitek, right?
A And the company.
Q That's two things, right?
A It was one project which involved a couple of different things.

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Q Two aspects of one project.
A Yes.
Q One of those aspects was evaluating Digitek.
A In my words can this company make Digitek right and can this company make anything right, in my words.
Q Can this company make Digitek right or did this company make Digitek right? What were you evaluating?
A Both.
Q So you evaluated whether the company properly manufactured Digitek?
A And whether I believe it is capable of doing it. I mean, it's more than one thing in the process.
Q I understand, Mr. Farley. Is one of the things that you evaluated whether Digitek was manufactured properly?
A Yes.
Q Is that also something that was the subject of your expert opinion, whether Digitek was manufactured properly?
A Yes.
Q Let's talk about FDA 483s for a moment.

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A Yes.
Q 483s -- well, you tell me what a 483 is.
A First I would like to define an observation is a violation.
Q Mr. Farley --
A Yes.
Q -- that wasn't close to the question I asked.
MR. MILLER: I disagree.
Q I asked you what a 483 form is.
MR. MILLER: But he's answering the question.
Start again where you were.
A I have to start with what an observation is because it's part of it.
Q I'm asking you what a form is. I didn't ask you what -- an observation is something that goes on the form.
A Oh. All right.
Q I asked you what the form is.
MR. MILLER: Well, if he's explaining to you what's on the form that's an answer.
Go ahead and answer just the way you were going to answer. Don't let him tell you how to answer a question.

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A Okay. Continuing on, the 483 is so called it because it's an FDA Form 483. But that form is a list of observations -- and I'm using that term interchangeably with violations -- that an inspection -- an inspector or inspection team observes when they inspect a facility.
Q Your testimony is that an observation on a 483 reflects an actual violation of what? Good Manufacturing Practices?
A Could be that.
Q Could be what else?
A A lot of times -- if it's a GMP inspection it -- if it's a GMP inspection, then it will be a GMP violation. There are pre-approval inspections. There are for cause inspections when someone says, hey, I think something is being done wrong at that plant. But if it's a GMP inspection then it will center on GMP violations.
Q But it's not an actual final determination of violation of GMPs, is it?
A It holds a lot of weight. It's the inspector's -- it's their jobs. They turn it in to a supervisory inspector. It goes to district director. Let me say it this way. In almost eight years at FDA I've never seen one changed.

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Q You've never seen one changed?
A I haven't, not in the Philadelphia district, which is one of the busier districts.
Q Did you review the revised warning letter that was issued in this case?
A I did.
Q So revised means that it was changed, right?
A I should have reworded that and said I've never seen one lessened. But, no. 483 is a list of observations. Let's say that I'm walking through your plant and I make observations.
Now, once I leave your plant, having told you of these observations, there's absolutely no reason I'm going to change anything. They're observations. They're facts. They're not opinions. They're facts.
Q This is not a great -- well, but you keep wanting to insist that there -- I think you testified a moment ago that you use the term observation and violation interchangeably.
A I do.
Q That's not correct, is it?
MR. MILLER: Object to form.
A Yes, it is correct.
Q Well, I asked you and I don't think you

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answered it directly.
A Okay.
Q An observation is not a final agency determination on whether the company has violated Good Manufacturing Practices, is it?
MR. MILLER: Objection, asked and answered.
MR. ANDERTON: It hasn't been asked and answered. He raised it unilaterally in responding to the question.
A Technically it's not. They're all subject to approval by the supervisory investigator. But I've never seen any supervisory investigator or district director change one.
Q But the answer to my question is an observation on a Form 483 does not -- does not represent the determination of the FDA as to whether GMPs have been violated.
A Yes, it does. It represents the opinion of that inspector or inspectional team who is representing the FDA.
Q Subject to review by several levels within the FDA.
A I think I maybe best say it if --
Q Is that true or not, Mr. Farley, before

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you -- you can answer that question.
A Not several levels, no. I wouldn't say several levels.
Q Two at least?
A Sometimes -- sometimes it's one.
Q FDA -- or observations on a Form 483 are written up by the inspector, the investigator, correct?
A Yes.
Q Not subject to review before they're issued?
A Not subject to review. Correct.
Q So they don't have to submit them to the compliance division, for example, before they're issued?
A Correct.
Q Mr. Farley, I'm going to hand you a document that's marked as Defendants' Exhibit 57. It's difficult to read the sticker.
A Yes.
Q Depending on your vision status it may be difficult to read some language we're going to ask you to read real quickly. But I'm going to give it a shot nonetheless.
A Okay.
Q Do you see that this is an FDA 483 issued to Actavis covering an inspection that occurred in

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September of 2007?
A I see it.
Q Is this one of the documents you reviewed as part of your rendering an opinion in this litigation?
A I believe it is.
Q Okay. I'm going to read the fine print, if you will, right below the heading on the first page there. And I'll -- if you'll follow along.
This document lists observations made by the FDA representative during the inspection of your facility. They are inspectional observations and do not represent a final agency determination regarding your compliance.
Did I read that correctly?
A You read it correctly.
Q That language is on all FDA 483 forms, isn't it?
A Standard.
Q So on its face this document makes very clear that observations on a 483 are not the final view of the FDA with respect to whether a company has complied or not complied with Good Manufacturing Practices; is that correct?
A My opinion is it's not the final view. It's what they're going to do about the company. Let it

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open, shut it down, ask them to recall. But it's not going to change their opinion about the company or whether they're in or out of compliance. What happens here, this then gets classified as OAI, VAI or NAI.
Q What's VAI mean?
A Voluntary action indicated.
Q That's a very positive outcome for an inspection, isn't it?
MR. MILLER: Object to form.
A Not really. NAI, no action indicated, is a positive outcome for an inspection. If you're a pharmaceutical firm you want everything to be NAI, no action indicated.
Voluntary action indicated means you're doing something wrong and they told you to make it right. But like a recall, technically it's voluntary. If you don't do it they're going to shut you down. But it's called voluntary.
And an OAI is official action indicated, which means if you don't do this we're really taking action immediately.
Q So, Mr. Farley, back to my question about this language, this form on its face says whatever is written on here is not final agency determination regarding compliance, doesn't it?

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A That's what it says to be polite, but why would they send someone out to inspect and write this on a form? They're not going to say, by the way, don't worry about it, we're not listening to what our inspectors say.
Q I understand that, Mr. Farley.
A The inspector carries weight with their opinions.
Q I understand that. But at the end of the day it is the first step in a multi-step process that ultimately determines compliance.
A It's probably in time invested 99 or more percent by weight right here in front of us right now, because the supervisory inspector gets the inspector, how is this, how -- now, the inspector has been talking on the phone in the meantime.
So the supervisory inspector knows, how is it going at such and such. Hey, I'm finding a lot of problems here, this is going to be a big one. So the supervisory inspector knows whether -- what to expect.
Then they come in. They look. Do you have it written up okay? Fine. Okay. Good. I mean, it isn't like you're going before a board of review that doubts the inspector.
Q I'm not suggesting that the --

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A Okay. I mean, I just wanted --
Q -- inspector won't have the support of the people above him or her in the hierarchy at the FDA. But it is not accurate to say that an observation is a violation because the form itself says otherwise.
MR. MILLER: Object to form. It misstates what the form says.
A Well, I jump to Observation 2 only because I can't read exactly Observation 1 because of the print. Observation 2, the written stability testing program is not followed. There's a violation of GMPs right there. I mean --
Q If it's true it could be a violation of GMPs. There are -- the company is permitted to respond to a 483, correct?
A They are permitted to.
Q And sometimes the company will submit facts and circumstances in response to the 483 that will result in an observation being withdrawn.
A I've never seen it happen.
Q Well, that just means that your experience isn't broad enough to have run into that, correct?
A That could be. Logically that could be. But I think I have reasonable experience and it would indicate that if it happens it's rare.

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Q Well, it happened in -- with respect to this company, didn't it?
A Did it?
Q Yes.
A I haven't seen it.
Q The revised warning letter that you read removed an observation when compared to the initial warning letter.
A The revised warning letter was after they responded and perhaps corrected -- I don't know -- perhaps corrected that.
Q Well, all warning letters are after they respond and correct.
A But I mean, suppose somebody says you have to straighten that out. You say, okay, I'll have that straightened out by next week. You have a violation at that time, but you straighten it out and you say, could you knock this off the letter, it doesn't exist anymore.
Q Mr. Farley, if it were that simple there would never be a warning letter, because everybody responds to a 483 and offers corrections in response to a 483. So why would a warning letter ever be issued if it were just as simple as it doesn't exist anymore?
A No. I'll tell you why.
MR. MILLER: Objection, misstates his testimony.

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A Because when you said everybody responds in a positive way, no, they don't. That's why some places are shut down. That's why there are consent decrees. That's why some people either don't know how or don't care. And so, no, not everybody responds to it in a positive way. They all like to think they do but they don't.
Q There are plenty of warning letters that are issued even though companies have responded in a positive way, correct?
MR. MILLER: Object to form.
A I'm not sure. I don't know the answer to that.
Q You're an expert in regulatory compliance. How can you not know the answer?
A I haven't read all the warning letters that were issued. I'd have to --
Q I'm not asking you to read all of them. I'm asking you based on your experience in holding yourself out as an expert in regulatory compliance, isn't it true that, that warning letters are often issued even though a company receives a 483, responds positively to the 483 and corrects the situation?
A I've never seen it happen and it should not happen.

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Q Never seen it happen?
A I have never seen it happen. I -- go ahead. Should I continue or --
Q The warning letters essentially say nothing more than what's in the 483, correct?
A The warning letter -- yes, it does say more. The warning letter says, you must respond in 15 business days --
Q Substantively --
A -- or we're going to take further action.
Q Okay. But that's the threatening part of the warning letter. But with respect to the substance of the warning letter and what it says about the facts and circumstances or the alleged violations, it's identical to what's in the 483, isn't it?
A I wouldn't use the word identical. It's -- a district director who looks over the 483 that the inspector and supervisor inspector have presented to him or her and determines if a warning letter is appropriate, these people really have to shape up, they're really not doing it good, I've got to have it where they must respond to this in 15 business days or we're going to take some other action like seizure or we're going to adjoin them.

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And it gives you a deadline and it reaffirms the importance of it. It's -- they're significant 483 items. And by significant I mean they can cause harm or danger to the consumer, the patient.

Q Are you familiar with the phrase Turbo --

A It's a new --

Q -- finding?

A -- system for generating -- I'm familiar with the phrase, but they did not use it when I was there.

Q So you don't have any experience with it?

A Only in reading it and seeing it's a more standardized format.

Q So if you're familiar with it then you know that all observations on FDA Form 483s are pre-drafted and that FDA inspectors must select from a pre-drafted -- what word do I want -- a pre-drafted sentence or sentences, pre-drafted language, in order to express an observation on a 483?

MR. MILLER: Object to form. That only pertains to a small portion of observation.

MR. ANDERTON: That's simply not true, Pete.

Q Do you know that to be true, Mr. Farley?

A That it has a particular format, pick one?

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Q Yes.

A I don't know all the details or all the forms, but I know that to be true.

Q Okay. So FDA inspectors go. They conduct an inspection. They make observations of things that they believe are not in compliance with Good Manufacturing Practices if it's a GMP inspection.

A Yes.

Q And they go and as they're preparing their 483 and listing the observation they select from essentially a menu of observations and they must use one of those menu options; is that correct?

A Yes, much like the policeman does if he stops you for speeding. He's got to --

Q Okay. So the inspector is on a 483 listing facts and circumstances that he or she believes violate the Act.

A Yes.

Q Isn't that the opinion of the inspector about whether there's a violation?

A The inspectors do not put opinions in a 483. This is grilled into you your first week at the agency. You put facts in there, not opinions.

Q The facts you put there must in your opinion violate the Act. You have to exercise some

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judgment, right, if you're an inspector and you're creating a 483?

A I feel like I'm getting into a play on words here and at the same time I'm trying to answer your question.

Q Well, you used, Mr. Farley, the example of a police officer.

A Yes.

Q If you're speeding -- if the speed limit is 55 and the police officer clocks you --

A Yes. 75.

Q -- you're either above or you're not.

A Yes.

Q And with respect to an FDA inspector, they're making judgment, exercise in judgment, in that moment about whether something complies or doesn't comply, right?

A Yes.

Q Judgment is very subjective, isn't it?

A I wouldn't call it that. If -- I guess one of the classic examples that I really had, someone inspected a plant and saw a bird flying through. And he said, this is unsanitary.

Well, technically in his opinion it was an unsanitary situation with the bird flying through a

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pharmaceutical manufacturing plant. And nowhere in the regulations does it say you shouldn't have a bird flying through, but it says appropriate hygienic material procedures must be there.

So an inspector goes in and looks, taking that somewhat way out analogy and coming down now and looks and says, this is the same initials of the analyst and the reviewer, that's a violation.

Now, I'm not calling that an opinion. I'm calling that a fact. But if you want to call it an opinion you can call it an opinion. But it's right there. It's right there in front of you. There's -- here's the initials, here's the initials. And that's it.

I've seen a case where somebody turned a wrong valve and ruined a 300,000-dollar batch of material. Well, nobody said, well, in my opinion you might have turned a wrong valve.

He did it. It's right there. It's all logged in. It's a fact. You can't ship that material. You ruined it. You know, I believe there are facts and I'm very reluctant -- in fact I'm resisting using the term opinion.

Q You did -- when you talked about the bird example you said that the inspector who saw the bird

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flying through the facility expressed his opinion that that was unsanitary.
A To show you that -- the fact is the bird went through, but there's nothing in writing that says the bird shouldn't go through. But I used the opinion, so --
Q Likewise, there is not necessarily anything in writing to suggest that somebody shouldn't -- well, if somebody turns the wrong valve there may not be something in writing to indicate that they shouldn't turn the wrong valve. They tell you which valve to turn, but there's no regulation that says don't turn the wrong valve.
A But there's an SOP that says turn that valve at that time, this valve at that time, that valve at that time. An SOP was violated. Therefore, it's a violation of GMPs.
Q When you talked about -- as you counsel clients in the industry do you tell them the Turbo language FDA inspectors are required to use to express an observation on a 483 don't always match up well with the facts and circumstances that caused the FDA inspector to write up that observation?
A No, I don't.
Q You've never told a client that?

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A No. I don't tell them that. I just tell them it's a violation and how they should keep things right.
Q So you don't discuss the process of 483s and what's on them and how to respond to them. Do you counsel clients on those subject matters?
A Oh, we discuss it. Most of them know a whole lot about it from having been in the industry for years and years and years.
Q When -- as I understand your testimony, you said the use of Turbo observations -- Turbo language on observations on 483s, that practice started after you left the FDA?
A Yes.
Q How long after?
A I left in '96. It might have started around 2000. I'm not sure when it started.
Q Okay. So it's been in place -- it was not in place up until three, four, perhaps five years after you left?
A Correct.
Q And what have you done to educate yourself about use of Turbo language as you hold yourself out as a consultant in the industry?
A I don't look at the Turbo program, per se.

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I look at what is written, if in fact the client had a 483 written. In many cases my clients didn't have a 483 and they just want to make sure that everything is still okay with them.
So the language of the Turbo program is not a primary concern. The content, the meaning of what an inspection is, how you make a good product, that is.
Q Do you counsel clients who have also received 483s?
A Sometimes.
Q You have to look at the Turbo language when you do that, don't you?
A Yes, I do.
Q You have to give your client guidance on what it means, what to do about it in response, right?
A Yes, I do.
Q They pay you a couple hundred bucks an hour to do that, right?
A Yes.
Q When you're giving that guidance you don't ever say to a client, well, it's not really the Turbo language you look at, it's the specific facts and circumstances you have to deal with?
How do you deal with the fact that the Turbo language doesn't always necessarily match up very well

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with the underlying facts and circumstances?
A They give you examples. Whenever they give you an observation they give you examples. And in the case of a client that had a problem, problem being non-compliance, a 483, I wouldn't do that over e-mail.
I'd say, when do I visit your plant, I want to see where this occurred, I want to see what's happening, I want to talk to the people that you have employed. That's -- I want to see for myself in addition to this so that I can match it up. And invariably it does match up.
Q Invariably?
A I haven't seen it where I saw something that disagreed with the 483.
Q Have you ever talked to FDA inspectors who were unhappy about the fact that in fact their choice of observation -- choices, I should say, of observation language, that they really feel their hands are tied because the facts and circumstances they observe aren't always covered very well or very squarely by the choices they have from the Turbo program?
A I haven't talked to any like that. I wouldn't be surprised if some do complain about that. There are people in workplaces complain about everything wanting to do something. But I haven't heard any of

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them.
Q And your testimony is that you've never -- that it's always true that the Turbo language used by FDA inspectors matches up with the facts and circumstances they cite?
MR. MILLER: Object to form, asked and answered, misstates previous testimony.
A It's -- my experience has been that it's always true that for the language they use, wherever they got it, Turbo or wherever or whenever, has always matched up.
Q Okay. I've handed you, Mr. Farley, a document that has been marked as Defendants' Exhibit 58. Have you seen that document before?
A I believe so.
Q That is the 483 issued at the end of the 2008 inspection of Actavis Totowa?
A Yes.
Q Will you look at Observation 2, please?
A On the first page?
Q Yes.
A I have it.
Q It reads, Drug products failing to meet established specifications and quality control criteria are not rejected. Did I read that correctly?

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A You read it correctly.
Q The first example they give relates to Digitek and specifically to Lot 70924. Do you see that?
A The first line, A?
Q Yes, the first example, Example A.
A I'm with you.
Q Okay. Why don't you take a moment. You don't have to read it out loud. But go ahead and read through just to refresh -- if you've seen this before I'm sure you read that. But refresh your memory and read the contents of Paragraph A, please.
A Just A?
Q Yes, just A.
A I read it.
Q Can you tell me in there where it says products that don't meet established specifications and quality control criteria were not rejected?
A The observation is drug products failing to meet --
Q I'm talking where in Paragraph A.
MR. MILLER: Well, he's stating what the observation is. So allow him to answer your question, Mike.
Q Go ahead, Mr. Farley.
A I'm more or less setting a flow to my

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answer. Can I still do that?
Q I apologize.
A The observation is drug products failing to meet established specifications and quality control criteria are not rejected. Now, I look at the bottom, no additional thickness testing or analytical evaluation of the double thick tablets. They didn't analyze it.
And no root cause was determined for the defect. However, the lot was released to the market by the quality unit in January of '08 following visual inspection. That's shoddy. That is really lousy for a pharmaceutical --
Q Mr. Farley --
A Oh, that's my opinion.
Q -- I asked you where in Paragraph A it indicates that a product that didn't meet established specifications was not rejected.
MR. MILLER: Asked and answered. He just told you.
MR. ANDERTON: No, Pete. He didn't come close to answering that question.
MR. MILLER: I disagree.
A I thought I did.
MR. MILLER: He gave you a perfect answer.

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A I thought I did. They didn't do additional testing and they didn't do a root cause analysis under the CAPA, Corrective Action/Preventive Action portion of the GMPs.
Q Wait. They didn't do a root cause analysis or they didn't determine a root cause?
A It says no root cause analysis and none was determined.
Q Okay. So it doesn't say -- wait, wait. Mr. Farley, I don't want you to get in a hurry here because this has to be precise.
A Yes.
Q It does not say no root cause analysis was conducted, does it?
A It does not say that.
Q It says --
A It says no root cause was determined.
Q So a root cause analysis was conducted; they just were unable to determine the root cause. And as you testified earlier, that happens, correct?
MR. MILLER: Object to form, misstates previous testimony.
A On occasion but they didn't do an analysis of the material. This is a powerful, dangerous -- they didn't analyze it.

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Q They didn't analyze what? The double thick tablet?
A Yes.
Q They analyzed them to tell that they were too thick and they rejected them.
A That's measurement.
Q Did those tablets go to market?
A No, but any responsible manufacturer would want to know is this double dose or is it the same dose disbursed. You want to know information about that to prevent it from happening.
Q Mr. Farley, I understand that. Did those double thick tablets go to market?
A To my knowledge, no.
Q They were rejected?
A But I don't know how many may have made it to the market that are not accounted for. That's what I wonder. That's --
Q That's --
A -- what they caught.
Q -- what you wonder?
A I wonder, yeah.
MR. MILLER: Well, that's what they caught. That's what he said.
MR. ANDERTON: It's not what they caught.

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Pete --
MR. MILLER: That's what he said. Read it back.
MR. ANDERTON: He said it's what they wonder.
MR. MILLER: And then he says -- well, please read back his last answer.
MR. ANDERTON: He never used the term caught.
MR. MILLER: Please read it back.
(The record was read back as requested.)
MR. ANDERTON: Because there was nothing about caught.
MR. MILLER: There was a word caught in there actually. But it's on the record like she said. Let's keep going.
BY MR. ANDERTON:
Q Mr. Farley, we're going to walk through this. Okay?
A Okay. There was one out in the market. A lady, a nurse or somebody in one of the documents found it.
Q From this batch?
A I don't know at this instant what batch it was from, but it was an oversized Digitek that she was

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distributing to patients in I'm going to say an old person's home, an aged home, aged facility. And she found it. And she contacted them.
Q What's the basis for that testimony? What is your basis for that testimony?
A The document I read.
Q Okay.
A It's in the documents that we copied.
Q Mr. Farley, so your -- well, let's focus on this for a moment. Okay? And I'd like you to stay focused on my question without interjecting your own testimony. Okay?
MR. MILLER: Objection, argumentative.
Q Mr. Farley, the first sentence, During the packaging of Digoxin tablets 70924 five double thick tablets were observed. That doesn't say anything about out of specification tablets not being rejected, does it?
A That one doesn't.
Q Quality assurance approved a 100 percent visual inspection of the 4.8 million tablet lot which resulted in an additional 15 double thick tablets.
Again, 100 hundred percent of the batch was inspected and they found 15 more tablets. That doesn't say anything about out of specification tablets not

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being rejected, does it?
A That as you worded it does not.
Q I just read the sentence, Mr. Farley. I didn't -- it wasn't my wording. That's the wording of the FDA, right?
A Yes.
Q So that doesn't say anything about out of specification tablets not being rejected, does it?
A Yes.
Q Am I correct about that?
A You're correct.
Q Okay. Although quality assurance was aware of double thick tablet findings, the batch was then released based on AQL sampling which included visual inspection of 1,330 tablets.
Again, it does not say out of specification tablets were released to market, does it?
A It does not say that.
Q No additional thickness testing or analytical evaluation of the double thick tablets was conducted. Focusing on the double thick tablets, which you already said were rejected, that sentence doesn't say anything about out of specification tablets going to market, does it?
MR. MILLER: Objection, asked and

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answered.
A It does not say anything about going to market.
Q Next sentence, no root -- well, or not being rejected, does it?
A Say that again.
Q Well, I -- never mind. We'll go to the next sentence. No root cause was determined for the defect; however, the lot was released to the market by the quality unit on January 28, 2008, following the visual inspection.
Again, it does not say out of specification tablets were released to market, does it?
A It does not.
Q Next sentence, No documented evaluation of the 89 -- approximately 89 lots that remained on the market at the time of the inspection. It doesn't say anything about out of specification tablets going to market.
A No, but it does in that sentence right there say they didn't bother checking the ones that are on the market to see if any got out.
Q It doesn't say defective tablets -- out of specification tablets were released to market, does it?
MR. MILLER: Object to form.

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A The way you have it worded it does not say that.
Q Okay. It's not my wording, Mr. Farley.
A I know.
Q It's the FDA's.
A I know.
MR. MILLER: Your last statement was your wording. It was -- you were not reading.
Q I'm talking about the sentence. That doesn't say out of specification tablets were released to market, does it?
A Correct.
Q So no sentence in that observation that relates to Digitek says out of specification tablets were released to marketing; yet the observation, the Turbo language, says drug products failing to meet the established specifications and quality control criteria are not rejected.
A I see it.
MR. MILLER: Hold on. He's reading it.
Q There's no question.
A There was no question.
Q Give me one second. Mr. Farley, I'm going to hand you a document that has been marked as Plaintiffs' Exhibit 158. We decided to leave some of

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the numbering on some of the -- some, not all, of the prior exhibits.
Have you seen that document before?
A I believe so.
Q Okay. This is an EIR, Establishment Inspection Report, relating to a 2007 inspection of Actavis, correct?
A Yes.
Q And Actavis Totowa, I should say.
A Yes.
Q Tell me what an EIR is.
A EIR means, as you just said, Establishment Inspection Report. It would be analogous to industry when you have a trip report. When there is an inspection and there are no observations or violations there's always a report, Establishment Inspection Report.
And in many cases, many that I've seen where there was a detailed inspection and the Establishment Inspection Report is the inspector as the head of the inspection team telling this is what we did, this is where we visited, this is what we looked at.
And if there's an EIR and there's no observations, that's as far as it goes. If there are observations then they are in effect excerpted from

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there and put into a 483. But that's -- before I digress too much, that's an EIR.
Q Well, that's actually not true, is it? Isn't the 483 issued at the close of the inspection?
A Yes.
Q At the close-out meeting?
A The typed-out version is not prepared at the close-out meeting. They are aware of what they're going to receive, but they may come back.
Q Is it your testimony really that the typed-out version of the 483 is not delivered at the close-out meeting?
A Not at the -- not in my experience, not at the very end of it. They -- the word is, we're having this typed up, it will be delivered to you. Now --
Q That makes me question your experience significantly, Mr. Farley.
MR. MILLER: Object to form.
A You're welcome to do that, but what I have seen is they say, we found this, we found this, they show the handwritten one, this is going back to get typed. That's my experience. And you're certainly welcome to question it, but I'll hold with it.
Q Can you turn to page 3 of Plaintiffs' Exhibit 158?

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A I have it.
Q While you have it, do you see the -- why don't you hold Defendants' Exhibit 57, which is the 483 that relates to this 2007 inspection, another document that I had given you previously.
A That one?
Q That's the one.
A All right.
Q Now, back to page 3 of the EIR, at the bottom, the second to last paragraph. It's not redacted. It begins, On 9/28/07 an FDA 483, inspectional observations, was issued to Mr. Apurva Patel, managing director.
A Yes.
Q So this indicates the 483 was issued at the close-out meeting.
A Then she did it in that case that day. I mean --
Q Will you look at -- well, she did the same thing for the 2008 inspection, didn't she?
A Could be district policy. District directors can choose their policy.
Q Okay.
A What I have seen is when they're shown written, they say we're going to come back. Now, when

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they come back you may call that a close-out meeting or others have just said we're coming to deliver the 483. But I don't view that as any contradiction of what I said. It just makes it non-universal. But you're getting the 483 either way.
Q What you said and what you said in your report is that observations from the EIR end up in the 483. It's actually the other way around. It's the EIR that's not issued until long after the inspection; isn't that right?
MR. MILLER: Object to form.
A No. It's not needed until after. If you have an inspection and you observed some good things and some bad things, you want to get the bad things out first to get them corrected and then you'll get the good things that are things they were doing well.
Q The good things would be an EIR, not the 483, right?
MR. MILLER: Object to form.
A Good and bad things are in the EIR, if there are any bad things.
Q Mr. Farley, turn in the Establishment -- in the EIR from the 2007 inspection. And again staying on page 3, do you see the first full paragraph?
A Which one?

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Q On page 3 the first full paragraph. It begins on 9/5/07.
A I see it.
Q Okay. And it describes the purpose of the inspection. And the third sentence reads, I explained that the purpose of my visit was to provide follow-up coverage to Warning Letter No. 07-NWJ-06.
And then it goes on to say also pre-inspectional -- pre-approval inspectional coverage -- there's some redacted language that the FDA redacted -- as well as GMP inspectional coverage.
Do you see that? Did I read that correctly?
A I see it.
Q Did I read that correctly?
A Yes, you did.
Q Okay. So the purpose of this visit -- this inspection, I should say, was to follow up on a prior warning letter; is that right?
A That's what it seems to be.
Q I'm going to hand you a document that's been marked as Plaintiffs' Exhibit 25. You see that this is a revised warning letter?
A Yes.
Q You see the number, the file number, on the face of the warning letter, 07-NWJ-06?

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A Yes.
Q Is that the same warning letter referenced in this EIR --
A Yes.
Q -- that is Exhibit 58?
A Yes.
Q So this inspection was to follow up on this one?
MR. MILLER: Object to form, misstates previous testimony. You read it in there, as well as GMP inspectional coverage. You seem to be forgetting half the sentence.
Q One of the purposes of this inspection was to follow up on this warning letter; is that correct?
A Yes.
Q You said you've seen the EIR that's marked Exhibit 158, right?
A This one?
Q Yes, that's the one.
A I've seen it. I reviewed it. I don't remember everything at this moment, but please ask me any questions you like.
Q By reviewed it do you mean to say that you reviewed it in the course of -- is it one of the documents you received from the Miller Firm?

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A Yes.
Q Is it something you reviewed in preparing your expert report in this case?
A Yes.
Q Give me one second. All right. Will you turn, Mr. Farley, to page 25 of Exhibit 158.
A Page 25?
Q Yes.
A I have it.
Q Will you read the first heading on that -- well, the first heading on that page reads Voluntary Corrections, right?
A Yes.
Q It goes on to read in the body of the paragraph under that, Corrections to the previous FDA 483 were reviewed with Ms. Wanda Eng, senior director corporate compliance for Actavis. The previous 483 observations in the associated corrections appear below.
A I see it.
Q So the FDA here is saying as part of this inspection we reviewed prior 483 observations and the corrective actions taken by the company, right?
A Yes.
Q And then they set forth pages of -- well, let's kind of go through some of this.

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A All right.
Q On page 25 the first observation relates to the quality control unit and the authority of the quality control unit.
Do you see that?
A I see it.
Q And then under corrections it first indicates that a number of individuals have been hired. It lists several -- it looks like the better part of 15 to 20 new hires. Do you see that?
A I see it.
Q On the next page, page 26, the first paragraph indicates that since the previous inspection the number of individuals in the quality assurance department has increased. It goes on to give the number but it's redacted. Do you see that?
A I see it.
Q And the rest of that page sets forth several paragraphs of additional corrective action, doesn't it?
A Seems to be.
Q Well, what do you mean seems to be? This is an FDA document, right?
A I have to read what we're correcting. I mean, the details. We said the quality control unit

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lacks authority to fully investigate. Then we jumped over to details of what was observed and we went right to the corrections. So I -- before I answer your question I've got to know more of what we're correcting.
Q Please read the details.
A You or me?
Q You. You don't have to read them out loud. You can just go ahead and read the paragraph of Observation 1 on page 25.
A You want me read out loud or --
Q No, you don't have to read it out loud. Just read it and let me know when you're ready to answer questions.
A It will just be a minute.
Q Take your time.
THE VIDEOGRAPHER: Mr. Mike, while he's reading that I'm going to go off the record and change tape.
MR. ANDERTON: Okay.
THE VIDEOGRAPHER: It is 2:15 p.m.
(A brief recess was taken.)
THE VIDEOGRAPHER: All right. We're back on record. It's 12 -- pardon me. It's 2:22 p.m. This is the beginning of Tape No. 5.
BY MR. ANDERTON:

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Q All right. Mr. Farley, we were talking when we left about Exhibit 1 -- what has previously been marked as Plaintiffs' Exhibit 158, the 2007 EIR. And we were talking about information on pages 25 and 26 of that document.
Have you had the opportunity to read the observation language that you were reviewing on page 25?
A Yes, I did.
Q And so then after that observation language is a page and a half of actions that the company took in order to correct deficiencies that might have been reflected in that observation language; isn't that right?
A I just pause. You said it might have been reflected. They're jumping out at me. That -- you're saying that might have been reflected. I'm looking at batches of drug products that have initially failed.
Q Mr. Farley --
A I mean --
Q -- we're going to be here a long time if you don't start answering my questions. My question was, is there a page and a half of corrective actions set forth on pages 25 and 26?
A Yes, there is.
Q Okay. Documented by the FDA in this EIR?

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A Yes, there is.
Q Okay. And accepted by the FDA?
MR. MILLER: Object to form.
A Implicit acception (sic) by the FDA since they wrote it.
Q Yes.
A Yes.
Q Next, page 27 -- well, let me ask you this, in the eyes of the FDA any deficiency that was set forth in Observation 1 is resolved by these corrective actions, right?
MR. MILLER: Object. It misstates the document.
A If they agree that it is resolved they could say -- and I'd have to refresh myself on the complete detail -- that here's your correction that you apply. They might say more is needed.
Q Do they say that with respect to Observation 1?
A I don't see it.
Q Okay. So in the eyes of the FDA any deficiencies that are reflected in Observation 1 have been corrected.
MR. MILLER: Object to form.
A An attempt has been made.

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Q I'm asking you about --
MR. MILLER: Object. He answered.
A I wouldn't know if they were corrected until I saw the subsequent batches that were manufactured and if these people performed their jobs properly.
Q Mr. Farley, I'm talking about in the eyes of the FDA -- well --
MR. MILLER: Object, asked and answered. He said it's been attempted. That's what's been done. He gave you an answer. You're badgering him.
MR. ANDERTON: Pete, you're not going to just shout me down and allow him to avoid answering the questions I ask him.
MR. MILLER: I'm trying to shout over you, Mike. And you've already asked and answered. He gave you an answer.
MR. ANDERTON: He has not given me an answer --
MR. MILLER: He has.
MR. ANDERTON: -- to the question and we're going to stay here until he does.
BY MR. ANDERTON:
Q So, Mr. Farley, I asked you a question.

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You've acknowledged that there's a page and a half worth of corrective actions that the FDA indicates were taken --
A Yes.
MR. MILLER: Objection, misstates previous testimony.
Q -- right?
A That there appear they're taking some corrective action.
Q Okay. And the FDA wrote this document, correct?
A Yes.
Q So the FDA wouldn't write this if it didn't believe these things hadn't happened, right?
A Correct.
Q And that's based on the inspection that is reflected in this EIR, right?
A Correct.
Q So the FDA comes in, they review circumstances related to a prior observation to see whether corrective actions have been taken.
A Yes.
Q And they issue this document which sets forth all of these corrective actions, right?
A Yes.

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Q And there's nothing in there indicating further action -- further corrective action is necessary for that observation, is there?
MR. MILLER: Objection.
A Nothing that I see.
Q Okay. Observation 2, page 27, do you see that language?
A Starting with laboratory records?
Q Yes.
A I'm reading it.
Q I don't want you to read it, but the observation is set forth and there are examples that go (a) through (g). Do you see that?
A Yes.
Q Again, that's language from a prior observation, right?
A Yes.
Q And on page 28 the FDA lists corrections. Do you see that?
A Top of 28?
Q Yes, sir.
A Yes.
Q So corrective actions were taken by the company in response to that observation, right?
A Yes.

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Q Does the FDA indicate any further action is necessary?
A Not at that point.
Q Observation 3, do you see that on page 28?
A I see it.
Q And do you see that it sets forth five, (a) through (e), five examples that support that prior observation?
A Yes.
Q Do you see there are corrective actions indicated at the bottom of page 28 and continuing on to page 29?
A Yes.
Q Does the FDA indicate any further action is necessary to correct that observation?
A They do not.
Q Observation 4 on page 29, and you see that there are again five, (a) through (e), five examples, supporting Observation 4?
A I see it.
Q Do you see at the top of page 30 corrective actions taken by the company?
A I see it.
Q Do you see -- does the FDA indicate any further action is necessary to correct that observation?

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A It does not.
Q Okay. Observation 6, still on page 30, do you see the observation?
A 6, bottom of 30?
Q I'm sorry. I misspoke, Mr. Farley. I jumped ahead and I apologize for that. Observation 5 in the middle of page 30.
A I see it.
Q Do you see that?
A Yes.
Q Do you see the corrective actions indicated by the FDA?
A I see it.
Q Does the FDA indicate any further action is necessary to correct that observation?
A They do not.
Q Observation 6 -- this time I mean it -- starting on the top of page 30, continuing on to page 31, and there are four specific examples, (a) through (d), supporting Observation 6.
Do you see that language?
A I see.
Q And do you see the corrections that the company took as indicated by the FDA in the EIR?
A I see it.

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Q Does the FDA indicate any additional actions are necessary to correct that observation?
A They do not.
Q I wish there was a way to make this shorter, Mr. Farley, but there is not. So I apologize.
A That's all right.
Q Mr. Farley, Observation 7 beginning on page 31, do you see that?
A I see it.
Q It carries over very briefly to page 32 and then there are three paragraphs relating to the corrective -- or reflecting, I should say, the corrective actions taken.
Do you see that?
A Where are we here?
Q Now we're on page 32.
A I see it.
Q And do you see -- and, for example, Mr. Farley, do you see the very first sentence of the second paragraph of the corrections on page 32?
A Beginning with, Corrections to the stability program?
Q Yeah. Read that sentence out loud, please.
A Corrections to the stability program have

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been verified during the current inspection.
Q So that's the FDA saying, we looked at this issue and we verified that the corrective actions have been taken, right?
A At that inspection, yes.
Q Okay. So does the FDA indicate any further actions necessary to correct the items set forth in Observation 7?
A No.
Q Observation 8, beginning on page 32.
A I have it.
Q Do you see that?
A I see it.
Q It carries over onto page 33 with -- again with five examples.
A I see it.
Q And then there are corrective actions indicated. Do you see that?
A I do.
Q Does the FDA indicate that there are any additional corrective actions necessary with respect to Observation 8?
A No.
Q Observation 9, beginning on page 33 and carrying over onto page 34 with three examples.

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Do you see that?
A Yes.
Q And again, corrective actions indicated in a paragraph about one-third of the way down on Paragraph -- or excuse me -- on page 34.
Do you see that?
A I see it.
Q Does the FDA indicate that any further actions are necessary to correct Observation 9?
A They do not.
Q Observation 10, beginning on page 34 actually and concluding on page 34. Do you see that observation?
A I do.
Q And there are corrective actions indicated on page 34 as well?
A Yes.
Q Any further actions necessary according to the FDA to correct that observation?
A No.
Q Observation 11, page 35.
A I'm with you.
Q Do you see any corrective actions indicated for Observation 11?
A I'm reading Observation 11.

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Q Take your time.
A Now I'm reading the corrections.
Q Take your time.
A And the question was?
Q Do you see any further actions necessary according to the FDA to correct Observation 11?
A No.
Q Observation 12 on page 36, do you see that observation?
A I see it.
Q And do you see the corrective actions indicated?
A I see it. I just want to read this one.
Q Take your time, Mr. Farley, whatever you feel is appropriate.
A I see it.
Q According to the FDA is that -- the items in Observation 12 corrected with no further action necessary?
A It appears to be.
Q Well, do they indicate any further action necessary to correct that?
A They do not.
Q And you said earlier that if there were further actions necessary they'd say that, right?

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A They would.
Q Observation 13, starting on page 36, continuing on to page 37, do you see that observation?
A I see it.
Q Do you see the corrective actions on page 37?
A Yes.
Q Does the FDA indicate any further actions are necessary to correct Observation 13?
A No.
Q Observation 14, do you see that?
A Yes.
Q Do you see the corrective actions?
A I'm reading.
Q Take your time.
A I see them.
Q Does the FDA indicate any further action necessary to correct Observation 14?
A They do not.
Q And finally, Mr. Farley, Observation 15.
A Yes.
Q Do you see that beginning on page 37 and continuing over briefly onto page 38?
A Yes, I do.
Q Do you see the corrective actions

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indicated?
A Yes, I do.
Q Does the FDA indicate any further actions are necessary to correct Observation 15?
A They do not.
Q So according to the FDA, corrective actions were taken in response to every single observation from the prior inspection.
A Taken or proposed? They hired new people, but you haven't seen them perform.
Q Were taken -- Mr. Farley, let's talk about you going down your own paths like that.
A Okay.
Q Taken means hiring. If you tell the FDA -- if the FDA cites you for not having enough personnel and you hire additional personnel you've taken a corrective action by hiring additional personnel.
A Right.
Q You don't need to see them perform to have taken the first step of the corrective action.
MR. MILLER: That's a different question. Why don't you ask him the question --
MR. ANDERTON: I didn't ask him that question. That's my point. He keeps interjecting his own thoughts.

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MR. MILLER: He keeps interjecting an answer and you keep stepping on him. Why don't you try asking a question and he'll answer the question.
MR. ANDERTON: I did ask him a question.
MR. MILLER: Well, ask him again.
MR. ANDERTON: Can you read the question that I asked before that back, please?
(The record was read back as requested.)
MR. MILLER: Can you read what the answer was, please?
(The record was read back as requested.)
MR. MILLER: And he was cut off. Would you like him to continue with his answer?
MR. ANDERTON: No, because he starts talking about them performing. That's not part of the corrective action. If the FDA --
MR. MILLER: Hiring somebody and their performance isn't part of a corrective action? Well, if you're asking if they just simply did something and didn't care what the outcome was then he's answering your question.
MR. ANDERTON: Well, there's a very precise reason why I'm asking that, Pete.
MR. MILLER: Well, ask it and he'll

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answer it.
MR. ANDERTON: I'm trying to get him to answer my --
MR. MILLER: You're trying to get the answer you want to get.
MR. ANDERTON: I'm trying to get him to answer my narrowly focused question.
BY MR. ANDERTON:
Q Did -- in the eyes of the FDA -- well, let me start that question over. According to the FDA corrective actions were taken in response to every single one of the prior 483 observations, correct?
A Yes.
Q And the FDA didn't indicate any further corrective actions necessary in response to any of those 483 observations --
A They did not.
Q -- did they?
A They did not. Could I explain my seemingly roundabout --
Q I don't think that's -- I mean no disrespect, Mr. Farley, but I'll ask the questions and then --
A Okay.
Q -- you go ahead and respond.

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A I just felt there was something important that -- but we'll go with the flow here.
Q When is the last time you were hired and retained by a pharmaceutical company to consult about GMP compliance?
A Probably last year sometime.
Q 2009, is that what you mean?
A Probably. I just don't remember. I'd have to go to their files.
Q Could it have been before 2009?
A Definitely it was before 2009. I think it might have been in 2009.
Q Okay. I mean the last time. When is the most recent?
A I don't remember that one offhand. I just don't, because I took a little time off to write the book and I did some other things. And I turned down a few. I really honestly don't know.
Q Okay. And just so that we're clear, you understand what final agency determination is, right?
A Yes.
Q A 483 is not final agency determination on GMP compliance, correct?
A Correct.
Q Nor is an EIR; is that right?

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A Correct.
Q In fact, a warning letter is not final agency determination, is it?
A Correct.
Q The FDA's perspective is to err on the side of caution as they engage in their regulatory activities, correct?
A I haven't heard it in those terms. If you're telling me that I would say that as a patient, a consumer, I would hope they would.
Q I'm asking you that as a regulatory consultant. Does the FDA approach its regulatory duties from the perspective of erring on the side of caution?
A The FDA as I have always seen its approaches is it don't err at all. They never mentioned -- if you're asking my perspective --
Q I'm not talking about err in the context of manufacturing pharmaceutical products. I'm talking about the FDA in performing its job.
For example, the FDA will ask a company to recall a product -- well, the FDA doesn't have to believe there is defective product in the market to ask a company to recall a product, correct?
A Do they have to? They don't have to.
Q They will ask a company to recall a

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product if they believe there's a possibility a defective product is in the market.
A If they believe there's a finite reasonable possibility that people can get hurt.
Q Well, that's not the question I asked, Mr. Farley.
A I'm really trying to answer it. I really am.
Q They'll ask a company to recall a product if they believe there's the possibility that there is defective product in the market.
MR. MILLER: Object to form.
A Yes.
Q You've seen that in your experience?
A Yes.
Q Mr. Farley, I'm handing you a document that has been marked as Defendants' Exhibit 39. And I will represent to you that it is a print-out of a posting on the FDA Web site. And you can see on the bottom right corner that it was accessed and printed on June 14th of this year.
A I see it.
Q Have you seen that posting on the FDA Web site previously?
A I don't believe so. I've seen a lot of

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them, but I don't believe I've seen this.
Q I understand. So you're not -- you don't think you have?
A Correct.
Q Will you read -- give me one second. Will you read the -- do you see the heading that says, If a Manufacturer is not Following cGMPs are Drug Products Safe for Use? It's about two-thirds of the way down the page, the first page. Do you see that?
A I'm pointing to it.
Q Okay.
A I found it. I see it.
Q I'm going to read the first paragraph under that heading. If a company is not complying with cGMP regulations any drug it makes is considered adulterated under the law. This kind of adulteration means that the drug was not manufactured under conditions that comply with cGMP. It does not mean that there is necessarily something wrong with the drug.
Did I read that correctly?
A You read it correctly.
Q Do you agree with that?
A Skeptically.
Q Skeptically yes?
A Let me think about that. It does not mean

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that there is necessarily something wrong. If I were writing that I would say -- this is if I were writing it and then -- that necessarily that there is something wrong but it may not be harmful.
There's something wrong because you didn't make it right; therefore something's wrong. That's what I would say. I disagree with the way this is worded.
Q So you would say it does not necessarily mean the product is unsafe.
A Or harmful, yes.
Q Or harmful.
A That's the way I would word that.
Q Okay. What's your understanding of why Digitek was recalled?
A Of why what?
Q Digitek was recalled.
A I believe that a lady died. I believe that there were numerous violations of GMPs and that there's no assurance that the product on the market wouldn't do harm. That's my opinion from what I've read.
Q You read that a lady died from Digitek, from taking Digitek?
A Somewhere I read it.
Q You read -- Mr. Farley, you read an

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adverse event reflecting an event that was reported from the market in sometime around 2000 and you believe that had something to do with a product recall that occurred in 2008?
MR. MILLER: Objection. You're putting words in his mouth. That has nothing to -- it's not even closely related. You've grossly misrepresented what he said.
A Go back to your question. Why do I think it was recalled?
Q Yeah.
A Somebody died from it years before.
Q How many years?
A Eight or ten.
Q And you think that had -- that related to the recall?
A No, no. It wasn't the end of my sentence. And in reading inspections and warning letters and looking not just at Digitek but at the company itself, I really question whether they can make anything right the way they were set up.
I didn't -- I agree with the consent decree. They're not capable -- were not capable of making a good product themselves. No guarantee of it.
Q Well, let's talk about operating under a

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consent decree. When you operate under a consent decree you're under incredibly close scrutiny, right?
A Yes. I have assisted firms operating under a consent decree.
Q Okay. Would you do me a favor and just close that laptop up? I don't need you distracted and there's no reason for it to be open anymore.
A Okay. I just --
Q I apologize.
A No, that's fine. It was distracting me, too. I just thought you wanted it on.
Q I don't need it on anymore.
A We're going to shut it down then.
Q Okay. Now -- all set?
A All set.
Q You say you've consulted for firms that have been operating under a consent decree.
A Yes.
Q Very close scrutiny when that happens, right?
A Yes.
Q Everything they do is watched.
A Yes.
Q If a company operating under a consent decree doesn't comply with GMPs, they're going to have

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big problems, aren't they?
A That's right.
Q They're not going to be able to release product, are they?
A They can't release it themselves. They need a third party approval. They're determined to be incapable of releasing it themselves when they're under a consent decree.
Q Well -- so if they're releasing product under a consent decree then they are complying with Good Manufacturing Practices.
A I hope so.
Q Well, they either are or aren't, right, Mr. Farley?
A That's right.
Q So they are?
MR. MILLER: Object to form.
A They should be.
Q If they're not they're not releasing product.
A I wouldn't doubt that some firms have released product when they shouldn't have.
Q But the third party has to approve.
A Oh, with the third party. Yes. The third party is the consulting function, usually a group of

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many consultants, who will determine whether the material is good enough to be released to the market.
Q Well, and you indicated a few moments ago that when you're operating under a consent decree you're operating with a third party looking over your shoulder checking everything you do, right?
A Yes.
Q So if you're releasing product while operating under a consent decree with that third party, you're complying with GMPs, aren't you?
A For those batches of that product.
Q For the batches that get released.
A Yes.
Q Any batch that gets released while you're operating under a consent decree is GMP compliant.
A If it went through the third party, if you didn't do it on your own and sneak it out, which some firms have been known to do.
Q Assuming you didn't sneak product out the back door --
A You did everything right, then the answer is, yes, it should be good.
Q So when you're operating under a consent decree for a long period of time you're actually engaging in sustained GMP compliance, aren't you?

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A While you're still trying to repair all your systems and get them in shape to do it yourself.
Q The answer to my question is yes.
A Yes.
Q You're operating under sustained GMP compliance, right?
A Yes.
Q Let's go back to the Digitek recall. You made -- when I asked you why Digitek was recalled you insisted on referring to somebody dying eight or ten years before the 2008 recall.
Do you believe that is one of the factors that resulted in Digitek being recalled?
A For the current recall?
Q Yeah.
A I believe it may have been in the minds of FDA when they asked Digitek to recall, but I don't know that. I have no way of knowing what was in FDA's mind other than the fact that they felt the product was unsafe.
Q Well, let's see if we can figure out what's in FDA's mind on that issue.
A Okay. I mean yes.
Q Mr. Farley, I have handed you a document that has been marked Defendants' Exhibit 38 and it is

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again a print-out of a posting from the FDA Web site. The date it was accessed and printed is June 15, 2010. And the title of the posting is "Facts and Myths about Generic Drugs".

A I see it.

Q Have you seen this posting before?

A No.

Q You have not?

A No.

Q Okay. Why don't you turn to page 2 of that print-out. And I'm going to read the first myth. This is a sheet, Mr. Farley, that -- it's kind of a publication put out by the FDA where they set forth something that might be part of public perception and then they set forth facts that the FDA believes kind of prove that perception incorrect.

A Yes.

MR. MILLER: Object to form.

Q Do you agree with that?

A I hear what you're saying.

Q Do you agree with that?

A That the FDA is putting this out to educate the consumer?

Q Yes.

A Sure.

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Q Okay. So -- and the education that's occurring is the FDA making an effort to correct misconceptions that might be out there.

MR. MILLER: Object to form.

Q Do you agree with that?

A That's what it says.

Q Okay. So let's look at page 2. Here is the myth the FDA is addressing in this instance. There are quality problems with generic drug manufacturing. A recent recall of generic Digoxin, paren, called Digitek, closed paren, shows that generic drugs put patients at risk.

Did I read that correctly?

A You read it correctly.

Q All right. That's the myth according to the FDA. The fact according to the FDA is, quote, FDA's aggressive action in this case demonstrates the high standards to which all prescription drugs, generic and brand name, are held, closed quote.

Did I read that correctly?

A You read it correctly.

Q I'm going to go on and there are four bullet points under that fact that the FDA set forth. And the first one reads, In March 2008 FDA performed a scheduled inspection of the Actavis production facility

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and identified products that were not manufactured to required specification over a period of time extending back to the year 2006. Included in this list of products was one particular lot of Digitek.

Did I read that correctly?

A You did.

Q Does that give you some insight into why the FDA started thinking about asking to recall that product?

A I'm not relating it yet.

Q Okay. Well, so far they're only talking about one lot, right?

A Yes.

Q And according to the FDA they encountered products not manufactured to required specifications and only one lot of Digitek fell under that description, right?

A Yes.

Q Okay. It goes on in Bullet Point 2 to read, Actavis detected a very small number of oversized tablets in this lot, paren, specifically, comma, 20 double sized tablets in a sample of approximately 4.8 million tablets, closed paren, period.

Did I read that bullet point correctly?

A Yes.

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Q So the FDA is still talking about only a single lot, correct?

A Yes.

Q 20 tablets out of 4.8 million. Is that a lot?

A Is it a lot? Numerically it's not a lot.

Q Statistically is it a --

A But I wouldn't want to be the one to take the oversized tablet.

Q Understood. But statistically is it a statistically significant number, 20 out of 4.8 million?

A A statistician -- and I'm not a statistician -- would probably say, no, it's not statistically relevant. But as a person in the pharmaceutical industry I look at a drug like this and I say everything counts.

It's like saying, well, some of the parachutes won't work. Well, I want one that works. I mean, I -- your question to me is very serious. And it is relevant. To a statistician it may not be.

Q Understood. Next bullet point -- and I misspoke. I said four. There's actually five. Next bullet point, quote, Although Actavis attempted to remove the affected Digitek tablets through visual inspection FDA determined that this method of removal

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was inadequate to assure the product's quality and consistency in accordance with the current Good Manufacturing Practice, and then cGMP in parentheses, regulations, closed quote.

Did I read that correctly?

A Yes.

Q So the FDA is focusing on the inspection method with respect to the double thick tablets for that single batch, right?

A Yes.

Q Having read those three bullet points, does that give you a better sense of why the FDA asked Actavis to recall this product?

A No, it doesn't really -- what it does, the first thing I see was shocked that they mentioned company names in here in what's supposed to be a public document.

Q Mr. Farley --

A They shouldn't do that. Yes.

Q -- that wasn't even remotely close to answering my question. Now, I would ask that you please --

A Okay.

Q -- answer my question.

A I will try. Please answer it -- I mean --

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MR. ANDERTON: Would you read that back, please?

(The record was read back as requested.)

A Does it give me a better sense than I have? No.

Q It gives a pretty detailed explanation of why the FDA -- what the FDA encountered and why they asked Actavis to recall Digitek. You're a consultant in this industry and those -- that doesn't tell you --

A Your question was does it give me any better sense than I had and my answer is no.

Q Well, you talked about a woman dying ten years before this recall and you talked about all kinds of other things.

The FDA is actually explaining why it asked Actavis to recall this product, isn't it?

MR. MILLER: Object to form.

A They're not telling the whole story. I believe the recall was based on systems not functioning, quality systems not functioning and quality assurance. Does this give me any better -- no, it does not.

Q Well, that's what you believe. This is the FDA telling the world why it asked for a recall on this product, right?

A But your question was does it give me any

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clearer understanding. My answer is no.

Q When I asked you that question earlier you said, I don't know why the FDA asked for that. And my question now is, does it give you a better sense of why the FDA asked for it? I'm not asking you your opinion any longer. I'm still trying to get you to answer why the FDA asked for a recall on this product.

I asked you that question about five minutes ago before we started reading this document and you said you didn't know. Now having read these three bullet points I repeat my question.

Does it give you a better sense of why the FDA asked for a recall on this product?

A It does not give me a better sense than what I had, that previous sense being that all the systems were not functioning properly.

Q Mr. Farley, that was the reason you gave why you thought the product was recalled. When I asked you earlier why the FDA asked for it to be recalled you said you didn't know.

A If that's what I said then that's what I said.

Q Okay. You definitely said that. So this doesn't help you? I mean, are you now telling me that you think your reason and the FDA's reason are the same?

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A They would be similar, identical overlap or whatever.

Q Why wouldn't the FDA say that? Why would the FDA make reference to a single lot and double thick tablets and the inspection protocol and the concern about the inspection protocol?

Why wouldn't they -- why would they fool the entire world with a public posting on its Web site available to anyone in the world and say, these things are the reason we asked for a Digitek recall, if in fact it was all of the things you believe?

MR. MILLER: Object to form, misstates previous testimony.

MR. ANDERTON: It doesn't misstate his previous testimony.

BY MR. ANDERTON:

Q You may answer, Mr. Farley.

A My answer is I don't know why they would do that.

Q Well, you worked for the FDA. They're not in the business of disseminating bad information, are they?

A They're not supposed to be, but this is surprising to me, this --

Q Would you have liked to have seen this as

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you were doing -- preparing your report in this case?
A If it's relevant information. And it seems to be. But I don't know that I'd change my statement to you.
Q Well, it's relevant information, though, right?
A Yes.
Q And it gives the FDA's position on this recall, doesn't it?
A Yes.
Q Bullet Point 4, Since the detection of the -- and I'm reading quoting now -- Since the detection of the manufacturing problem FDA has been actively engaged with this company to ensure that all potentially affected lots of Digitek have been recalled. In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely, closed quote.
Did I read that correctly?
A You read it correctly.
Q So did you consider adverse events -- the historical pattern of adverse events as you prepared your report in this case?
A I reviewed files relating to adverse

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events.
Q You reviewed FDA 483s. Do you know how many adverse events for Digitek were received in, say, the five years before the recall?
A I don't know the exact number.
Q Because you didn't ask and you didn't review that information, did you?
MR. MILLER: Object to form.
A I didn't ask and review.
Q Would you have liked to have known as you were preparing your report that the FDA thought that harm to patients was very unlikely?
A I would like to know -- if I was talking to someone at the FDA I would like to say, how come you say it's very unlikely and you tell them to do a Class 1 recall, which means that it's very likely? The Class 1 recall means harm to the patient is likely and you put on your Web site, FDA. Who did you hire to put this out?
Q Harm to the --
A That's a contradiction.
Q A Class 1 recall means harm to the patient is likely if they get a defective tablet. You've got to put that step in there, right, Mr. Farley?
A And if you buy or use the product you have

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a possibility of getting a defective tablet.
Q I understand. But you must first have defective tablets, right?
A Defective in any a number of ways --
Q Okay.
A -- not just oversized.
Q What other defect are we talking about?
A It could be over-strength, under-strength. I don't trust their results.
Q Don't trust whose results?
A Digitek -- or Actavis.
Q Does the FDA say anything about anything other than double thick tablets?
A No, they do not.
Q So the FDA was on site conducting an inspection and asked the company to recall that product, right?
A They asked them to do a Class 1 recall, which means that harm is likely. And whoever --
Q Harm because --
A -- does this says it's unlikely and it's a contradiction.
Q Okay. But, Mr. Farley, you didn't answer my question. The FDA was on site conducting an inspection and asked the company to recall this product,

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correct?
A Yes.
Q Asked them to recall all lots, right?
A Yes.
Q Here they are explaining the reason why they did that, referring only to double thick tablets in a single lot. Do you see that?
A Yes.
Q And yet you don't think that's the real reason the FDA asked for this recall?
A No. I see a contradiction between this -- I read -- I see it. You showed it to me. It's right here. I see this and I see what I read and I see a contradiction. If it's unlikely why do a Class 1 recall?
Q It's unlikely because it's unlikely any defective tablets made it to market, Mr. Farley.
A Then why would they do a Class 1 recall?
MR. MILLER: Wait. That's not a question. Wait for a question.
Q Mr. Farley --
A Yes.
Q -- you understand what a Class 1 recall is.
A Yes.

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Q I mean, you're a consultant in this industry, right?
A Yes.
Q It's based more on the nature of the product --
A Yes.
Q -- than on the likelihood of there being defective product. If there's any -- we established earlier that if there's any possibility that defective product made it to market the FDA will aggressively ask for a recall, right?
A Yes.
Q And if you have a product that has -- that is of the right nature and characteristics and there is any possibility that defective product made it to market, then that becomes a Class 1 recall, right?
A If there's possibility of harm to the patients.
Q Right.
A There's Class 1, Class 2 and Class 3.
Q I understand. So this drug, the nature of it is such that if you get a defective tablet -- I don't think anybody disputes -- you could potentially be harmed.
Do you agree with that?

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A Yes.
Q But the FDA is making very clear, again, in a public announcement regarding this recall, it made the request for a recall because there were 20 double sized tablets in a single lot.
A Uh-huh.
Q Do you see that?
A Yes.
Q So we now have a lot more insight into why the FDA -- when you first said I don't know and I introduced this document, we now know why the FDA asked for this recall, don't we?
A This contradicts what I read.
Q What you read was a recall announcement and combined with the general standards for a Class 1 recall.
A Uh-huh.
Q I don't think the FDA is saying here if you've got a defective tablet there's no possibility you'll be harmed. But they're very clearly saying, we don't think you -- there's a likelihood that you got a defective tablet, aren't they?
MR. MILLER: Object to form. The document speaks for itself.
A That looks to be what they're saying. Who

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signed it? Who wrote it?
Q It's posted on the FDA Web site. Do you think a computer hacker got in and --
A Not necessarily a hacker.
MR. MILLER: Objection, argumentative.
A But I would wonder really because the way that's written.
MR. ANDERTON: What time did we start this session?
THE VIDEOGRAPHER: This session was started at 2:22, sir.
BY MR. ANDERTON:
Q Mr. Farley, I've handed you a document that was marked in a prior deposition as Plaintiffs' Exhibit 106.
A Yes.
Q Do you see that?
A Yes.
Q You've seen that before?
A Yes.
Q It was a pretty significant document to you, wasn't it?
MR. MILLER: Object to form.
A Every document is significant to me.
Q Well, you gave this one a lot of weight

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when you prepared your report, didn't you, Mr. Farley?
A Let me glance through it.
Q Take your time.
A I'm reading -- one of my questions when I reviewed this was who wrote it. There's no signature. But I just mentioned that. I'm prepared to answer your question.
Q My question is, you gave this a lot of weight when you wrote your report, didn't you?
A I gave them all a lot of weight.
Q You gave this one particular weight.
A If you say so.
MR. MILLER: No, don't let him say so.
A I mean, I -- to my knowledge I looked and felt what I thought was important and I tried to look at everything as best I could. I'm not sure -- did I give it a lot of weight? I gave them all a lot of weight.
MR. ANDERTON: Did somebody take my copy? Oh, there it is.
Q Your report contains an explicit analysis of this document in particular, doesn't it?
A Yes.
Q Okay. So I actually like your question, Mr. Farley. Who wrote this? Do you know?
A Are you asking me or are you agreeing --

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Q I'm asking you.
A -- that's a good question? It's on Actavis' letterhead.
Q Do you know who wrote it?
A I do not know who wrote it.
Q You describe it in your report as correspondence. Do you know that it's correspondence?
A A memo, correspondence. I mean, it's from someone at Actavis reporting on a close-out meeting.
Q A close-out meeting is a meeting that occurs at the end of an FDA inspection.
A Yes.
Q And on page 20 -- I'm sorry. On page 17 of your report you have an entire paragraph devoted to commenting about this. And in particular you focus on the term "total failure" that appears in the third full paragraph on page 1 of Plaintiffs' Exhibit 106.
Do you see that?
A Yes.
Q Your comment is, To have a total failure such as this indicates that there is no product of this company at that location that can be relied upon to be of the proper identity, strength, quality and purity acceptable to the FDA as being safe for the consumer.
A Yes.

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Q You've said multiple times during this deposition that you believe -- that you didn't believe in anything that this company released, right?
A I wouldn't trust anything that company produced as being safe.
Q Is that because this document suggests there was a total failure of the quality system?
A That and -- well, pretty much all the documents contributed in one way or another to what I wrote. This one I quoted from.
Q What does total failure mean in the context of this document?
A No reliability on any of the steps in their production system.
Q Were you at this meeting?
A No.
Q Did you talk to anybody who attended it?
A No. That's why I quoted from it.
Q Well, you quoted --
A I wasn't there.
Q I understand. But do you know what the person who prepared these notes meant?
A I assume a total failure means total failure.
Q With respect to what?

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MR. MILLER: Objection. The document speaks for itself.
A The production of pharmaceutical products.
Q That's not what this document says.
MR. MILLER: Take your time and read the paragraph.
A From the quality systems standpoint.
Q But total failure of what aspect of the quality systems? Does this document say that?
MR. MILLER: Object to form.
A Total failure means --
MR. ANDERTON: Pete, what's your --
A -- total failure.
MR. ANDERTON: -- objection on that question?
MR. MILLER: My objection is you're taking it out of context. You need to read the whole sentence. It's vague, asked and answered, argumentative. Let's take it from there.
MR. ANDERTON: Would you read my question back, please?
(The record was read back as requested.)
MR. ANDERTON: All those objections to that question, Pete? Really?
MR. MILLER: Yeah, leave them on there.

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What the heck. You can keep asking.
BY MR. ANDERTON:
Q So notwithstanding Mr. Miller's frivolous objections, I repeat -- I ask you to answer my question, Mr. Farley.
MR. MILLER: And he did.
A Would you repeat the question, please?
MR. ANDERTON: Would you read it back, please?
(The record was read back as requested.)
A I read total failure as total failure, meaning there's nothing you can rely on as doing what it's supposed to do. Now, if you say of what aspect, well, then we're talking about partial failure.
Q But that's your read of this document.
A That's my reading of this document. Total failure, I mean, you look at that and you say, this company isn't doing anything right.
Q What context was this in? Were you there?
MR. MILLER: Objection, asked and answered.
A I was not there.
Q So you place -- to reach that conclusion you're placing heavy reliance on the words in this document?

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A I place heavy reliance on words of any document that comes to -- that's given to me to review and it's an exhibit. So, yes, I do, but not because of one thing or another, because it was there or anywhere else.
Q We can agree, Mr. Farley, that your comments in at least Paragraph A on page 17 are based entirely on this document. Take your time.
A I wrote it but I want to review it to be sure.
Q Please take as much time as you think is necessary.
A Section A was based on this document.
Q Entirely?
A Yes.
Q In order to have a true understanding of the total failure comment in this -- that this document reflects was made in this meeting you have to be at the meeting and hear the context in which it was made, wouldn't you?
A I believe that helps anywhere if you're present and you feel the full context. So I'll give an agreement, not just on this but any situation.
Q So the answer to my question is yes.
A Yes.

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THE VIDEOGRAPHER: I'm going to go ahead and change tapes, sir.
MR. ANDERTON: Okay.
THE VIDEOGRAPHER: We're off record at 3:20.
(A brief recess was taken.)
THE VIDEOGRAPHER: All right. We're back on record. It's 3:24 p.m. and this is the beginning of Tape No. 6.
BY MR. ANDERTON:
Q Mr. Farley, I'm going to hand you a document that has been marked as Defendants' Exhibit 20. I don't know whether you've seen that document before, but take a moment to look at it and let me know when you're ready to answer some questions about it. And I will let you read sections necessary to answer any questions I might ask.
A It doesn't look familiar, so --
Q Okay.
A Thank you.
Q Are you ready to -- you want to -- are you ready to talk about it or do you want to --
A I'd like to glance through it.
Q Take your time.
A This should be fast enough?

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Q What's that?
A Am I going fast enough?
Q Are you ready to answer some questions about it?
A As you see I've not read it, but I think that I can -- if you'll grant me if I'm stuck I'll go to a section.
Q You may take, as Mr. Miller says and I agree with, you may take as much time as you think is necessary to answer any specific question.
A Then I say let's start when you're ready.
Q All right. So you say you don't think you've seen that before. Does your review change that, that opinion? Do you think you've seen this document before?
A I'm vague. I saw so many. I saw 93 of them. Some of them I could say definitely yes, maybe a few definitely no. I just don't know. I'd have to --
MR. MILLER: And if I could add something to that. This was just sent to me. I saw it for the first time last week. And I believe I brought a copy and there's probably a copy in Mr. Farley's file. But I just received it.
MR. ANDERTON: I understand that. I know that to be true. So that doesn't surprise me.

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MR. MILLER: So I think he has a copy, but I don't think he's gotten a chance to actually read it.
MR. ANDERTON: Understood.
BY MR. ANDERTON:
Q And whether you've seen it before is more formal or substance than anything, Mr. Farley.
A Thank you.
Q Do you see and based on your experience in the industry and as a consultant in the pharmaceutical industry that this is an EIR relating to a 2004 inspection of Amide Pharmaceutical?
A I see.
Q You agree with that, right?
A Yes.
Q Okay. And you know from your involvement in this case that Amide Pharmaceutical is -- was the predecessor to Actavis Totowa?
A Yes.
Q And they are the original holder of the NDA -- excuse me; I misspoke -- the ANDA for Digitek?
A Yes.
Q Will you turn to page 4 of this EIR, please.
A I'm there.

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Q And I'm going to read from the -- there's a heading, History of Business, slash, Operations. I'm going to read some of that paragraph. Amide Pharmaceutical, comma, Inc., is a privately held family owned organization which has been in operation since 1983.

Divya Patel, comma, President, comma, stated that the company has undergone significant changes, especially following the consent decree of permanent injunction in 1992. The site was shut down for one year in 1992. The consent decree was lifted in 2001 following successful demonstration of sustained cGMP compliance.

Did I read those several sentences, correctly?

A Yes.

Q In your report on page -- well, on page 19, the fourth -- I'm sorry -- the third conclusion on page 19 that you offer reads, To be under a consent decree for more that -- and that's a typo I suppose -- that should be than --

A That's a typo.

Q -- ten consecutive years is an indication of continuing serious problems with FDA regulations.

Do you see that sentence?

A I see it.

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Q Did I read that correctly?

A Yes.

Q Well, they weren't under a consent decree for more than ten consecutive years, were they?

A I believe it was nearly ten consecutive years. So more than would not be correct.

Q Okay. So that's inaccurate and you got bad information apparently.

A Apparently on that one.

Q Okay. And we talked earlier about what it means to be under a consent decree and you agreed that if you're under a consent decree you're actually engaging in sustained compliance with cGMPs, aren't you, with current Good Manufacturing Practices?

MR. MILLER: Objection, misstates previous testimony.

A You are obligated to have third party review and release any product you make.

Q You're ultimately performing all of the activities to put those products in the position where you offer them for that review and release, right?

A Through the third party. They're actually doing some of the work for you.

Q They're not running machines for you. They're not --

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A They can.

Q -- testing products for you.

A They can.

Q The product is being manufactured and offered for release under your name, correct?

A Yes.

Q You're ultimately responsible for that product.

A Yes.

Q The third party doesn't have any responsibility.

A The third party has responsibility to you the pharmaceutical company. I wouldn't say they don't have any responsibility.

Q Your testimony -- I didn't say they had no responsibility. They're not ultimately responsible for the product in the market, for the quality of the product in the market. That responsibility always rely with you the manufacturer, correct?

A Ultimately, yes.

Q And your testimony -- and the record will reflect what you said earlier. But you said that if you're operating under a consent decree with that third party oversight your -- you must comply with Good Manufacturing Practices.

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MR. MILLER: Object to form, misstates his testimony.

BY MR. ANDERTON:

Q Because otherwise -- if you're releasing product you must comply with Good Manufacturing Practices because you can't release it without compliance, right?

A That's correct.

Q And this EIR indicates that the reason the FDA agreed to lift the prior consent decree that wasn't ten years -- wasn't more than ten years as you indicate in your report, because of successful demonstration of sustained cGMP compliance.

Is that accurate?

A Yes.

Q So when you say if you're under a consent decree for more than ten years -- forget the fact that the time is wrong -- and that that's an indication of continuing serious problems, the FDA apparently indicates that you -- that this company actually was successfully demonstrating sustained cGMP compliance, right?

A Yes. However, my experience in assisting firms to work their way out of a consent decree is that it normally takes one to two years to do it. And even

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though I said more than ten and it's nine plus, just under ten, that's still three or four times the normal amount.

So while the third party is putting the approval on the product it leads me to wonder why does it take them so long, admittedly not over ten but just under ten, why does it take them so long to work their way out? That's what I'm wondering.

Q Well, and so that we're clear, you're offering a conclusion that there are continuing serious problems with FDA regulations in your report, but now here today you're wondering whether they had serious problems with FDA regulations? You're wondering why it took so long?

A Wondering is a term I'm using in this discussion. I am very sure it had serious problems. They had trouble fixing them. And why does it take a firm more than eight years, more than nine years to repair something that other firms repair in one or two?

Q What documents did you review that relate to Amide's manufacturing operations during the period 1992 to 2002?

A I would have to go through the whole list of the 93 to answer that question.

Q Did you review any?

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A I quite likely did. It's all in the list in the report.

Q Let's take a look at that. Starting on page 8 of 27.

A Yes.

Q Mr. Farley, would you walk -- or work your way through the documents in that list -- and you testified earlier that this is the entire list of documents you reviewed to prepare this report, correct?

A Yes.

Q Will you work your way through that list and identify all documents that relate to or reflect manufacturing operations of Amide during 1992 to 2002?

A Of Amide.

Q Correct.

A I'm going to skip --

Q I want you to work your way through it and you can identify them. You can do it however you like. But I want to know about every single one.

A All right. In order to identify them as I present them to you, should I point or name them or --

Q You can name them. You can simply name them.

A I'm looking now for the name Amide as my key to answer your question. I see the distributing

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agreement, Mylan/Amide distributing agreement. I'm on the second page halfway down and I'm looking for complaint for permanent injunction and consent decree for permanent injunction. And I'm saying I believe that would be part of the answer, but I'd have to pull it up.

Q Well, I can represent to you that those two documents relate to Actavis in 2008 and not the Amide consent decree that we've talked about.

A I'll move right on.

MR. MILLER: I object to that.

A I'm on page 11, the second line or area of -- Amide's FDA inspectional history, March 23rd, 1992 to March 31st of 2004.

Q Okay.

MR. MILLER: What was the number of that document?

THE WITNESS: Plaintiffs' 235.

A On page 13 near the top, Plaintiffs' 241, a letter from Jasmine Shah, Amide. Do you see where I'm pointing?

Q Yes. Is that -- is that during 1992 to 2002?

A 2004 is later than 2002.

Q Okay.

A I was going to say the one immediately

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following Plaintiffs' 128, but that's 2004, which is later than 2002. And the following one is 2004. Those three in a row relate to someone questioning Jasmine Shah and him answering them. But they're all after 2002. I've done the table.

MR. MILLER: You indicated you were looking for the word Amide. You jumped over the word Amide in Tab No. 6.

MR. ANDERTON: Pete.

MR. MILLER: He indicated he was doing a word search.

MR. ANDERTON: Pete, do you want to let him testify?

MR. MILLER: I'm helping him with his word search.

MR. ANDERTON: You're helping him with his testimony.

MR. MILLER: No, I don't believe so. He was very clear, I'm going to go down the list and tell you every time I see the word Amide. He missed it. All right. Do you want facts or do you want --

MR. ANDERTON: Pete, I want you to not testify for him.

MR. MILLER: I'm not going to testify.

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You can go ahead.
MR. ANDERTON: We can give you an oath and have you sit in that chair if you like.
THE WITNESS: I didn't flip to that page because I'm not sure if I should or should not.
MR. MILLER: That's fine.
MR. ANDERTON: Which page?
THE WITNESS: Whatever he said that I --
MR. ANDERTON: You may flip to whatever page you like, Mr. Farley. I --
THE WITNESS: Apparently I skipped a Plaintiffs' something; although I thought I went down the whole list.
MR. MILLER: You indicated you were looking for the word Amide. And, Mr. Farley, you passed over the word Amide on Tab No. 6.
MS. DOWNIE: Of course, it's the wrong time frame.
MR. MILLER: I have no idea what time frame.
THE WITNESS: I passed over it. I passed over that because it was January of '07.
MR. MILLER: I have no idea of the time frame.
THE WITNESS: So I'm going to hold with

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what I finished --
BY MR. ANDERTON:
Q What you've identified?
A Yes.
Q There were four or five documents.
A I lost count but, yes, there were a couple.
Q Okay. And so let's look at those documents. The first one you identified is the very first one on page 8, the Mylan/Amide distributing agreement.
A Yes.
Q Well, will that give you any insight into where Amide was complying or having difficulty complying with FDA regulations?
A That would not.
Q The next ones you identified were 20 and 21. And I will tell you that those have nothing to do with Amide but are instead the complaint and the consent decree for Actavis.
MR. MILLER: And I'll object. The documents speak for themselves.
MR. ANDERTON: Yeah, and what they say, Pete, is that they relate to Actavis in 2008, not Amide in 1992.

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MR. MILLER: And I believe there's a little bit of repertory history in those documents. I don't have them in front of me, but I think the simple answer is the documents speak for themselves, Mike.
MR. ANDERTON: Okay.
BY MR. ANDERTON:
Q And the next one you identified was on page 11, Mr. Farley, Plaintiff's Exhibit 235. What is that document? Do you know?
A Amide's inspectional history.
Q Do you know what that is?
MR. MILLER: Why don't you allow him to get the document. He brought it for you.
Q As we sit here -- I mean, I have it if I want to ask you questions about it specifically. Do you know from looking at this document what it is?
A It says it's an inspectional history and it is quite likely an inspectional history. But to take that one out of 93 documents and answer specific questions would not be fair to give you an honest answer.
Q I understand. What is the next document -- well, is it accurate to say -- if you turn back to page 19 and that third conclusion, is there any

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source of information other than the documents you just identified which would have allowed you to form the opinion reflected in that conclusion?
MR. MILLER: I'll object. In all fairness I think he ought to see that document before he's asked a question about it.
MR. ANDERTON: I'm asking him if there are any additional documents besides the ones you've identified.
A Not a document but the fact that it was just under ten years and such a long, long time to be under a consent decree, which is very expensive and embarrassing, that opens your eyes as soon as you see that.
Q It opens your eyes in as a consultant, an expert consultant in this industry, it would prompt you to want to see more information, wouldn't it?
A Yes.
Q And so before, as you said earlier, before you could opine about compliance issues for that period or any period, while the consent decree might open your eyes you'd say, I'd want to see more information, right?
A Yes.
Q Are you familiar with the FDA surveillance program?

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A I've heard of it. And honestly at different times it's had different meanings over the years. So if you could tell me which surveillance program --

Q Are you familiar with the fact that the FDA -- do you know what an FDA 484 is?

A 484?

Q Yeah.

A I'm not familiar with a 484.

Q You're not familiar with a 484?

A I'm not familiar with a 484. I may know it not as a 484. Sample request. Is that the sample request form?

Q Yes.

A I just didn't call it the 484. That's a sample request where they come in and take samples periodically and then analyze it.

Q And test the product --

A I just blanked out on the 484 number and in a matter of seconds it came to me.

Q Okay.

A I'm not one to memorize 4 numbers too much.

Q That's okay.

A But it did come to me.

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Q Did Plaintiffs' lawyers tell you that Digitek was routinely tested by the FDA as part of its surveillance program?

A No, but it's not surprising that they would be.

Q Okay. But you didn't know that as you formed your expert opinion in this litigation?

A I would have assumed it. I mean, we did surveillance in Philadelphia. They went out to SmithKline and Merck, brought them in. That surveillance program apparently is the same surveillance program we're talking about. And the 483 is the sample. So, yes.

Q And your understanding -- well, do you have an understanding of the surveillance program that's conducted under the auspices of the 484s that allow you to take a sample? What is your understanding?

A There are periodic checks of samples as they would be going to the marketplace.

Q Samples taken from the market.

A In effect, random. We could use the term random.

Q Well --

A But I mean -- okay.

Q Are they ever taken from the market,

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from --

A Yes.

Q -- a pharmacist?

A Sometimes from a pharmacist and sometimes -- and I'm pausing because there are imaginary people who will get a prescription. In other words, it will be John Jones. And there is no John Jones, but they may order it over the Internet and have a post office box.

And they'll take this prescription for John Jones, who is a non-existent person, but it represents a prescription that was obtained over the Internet or through other means and analyze it.

Q Alternatively, the FDA can just show up at a pharmacist and issue a 484 and take a sample, can't they?

A They can.

Q Okay. And they do.

A They can.

Q And they do.

A They do.

Q Okay. And they did that while you were employed by the FDA from time to time.

A They did.

Q And it sounds like your lab was involved

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in testing some of those samples.

A That's part of what we did.

Q Okay. And so if you thought Digitek might be part of the surveillance program as you were undertaking your responsibilities in this engagement for this litigation, why didn't you ask to see documents related to that to see how Digitek had performed?

A It didn't occur to me. It didn't occur to me.

Q You were evaluating Digitek. Wasn't one of the things you might want to know, how the FDA came down in its surveillance -- or what the results of the FDA surveillance program relating to this product were?

A In retrospect any additional information could have been helpful, but I didn't feel it necessary.

Q So you had formed an opinion based on your review of a FDA document. You didn't actually want to be bothered with the facts of the product in the market. You just wanted to look at FDA documents.

MR. MILLER: Object to form.

A No. I would not put it that way.

Q How would you put it?

A I wouldn't be bothered to do it. I'm not in agreement with that choice of words. I was evaluating a situation. And I believe I had, after

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asking for more and getting more, sufficient documents to do my evaluation. And I wrote it. Right here.
Q To formulate a thorough opinion, if you knew Digitek was part of the surveillance program and consciously chose not to ask for that information, do you feel you've given a thorough evaluation -- if one of your pharmaceutical clients asked you to evaluate one of its products and you thought about whether it was part of the 484, the surveillance program, wouldn't you ask them to see that information?
A Yes, I would.
Q But you didn't here?
A I didn't. I didn't know the surveillance program as it related to them. And I don't work for the FDA anymore. I would not have ready access to that information.
Q You can get it through FOIA.
A I can get what?
Q You can get it through FOIA.
A We come back to the fact that I thought I had sufficient information here.
Q But if you were counseling a client you wouldn't think you had sufficient information. You said you would want to see and ask for the surveillance program results, right?

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A Probably that would be my viewpoint if I were counseling a client, yes.
Q Okay. So your analysis here is narrower because of the perspective you're taking.
MR. MILLER: Object to form.
A If you're saying -- if you're Plaintiff versus Defendant and which one, you might -- I would probably think of other things in carrying out my assignment.
Q Well, but I want to make clear, you said your analysis here is narrower and you don't -- there's information out there that you didn't consider and don't feel you need to consider because you're working for plaintiffs, correct?
MR. MILLER: Object to form.
A I didn't say my analysis was --
MR. MILLER: It misstates previous testimony. While I'm objecting you've got to hold on until I'm done --
THE WITNESS: Oh, I'm sorry.
MR. MILLER: -- and then you can answer. I'm going to object. It misstates previous testimony. Now it's okay to answer.
A I mean, I didn't say it was narrower. I think you said it was narrower.

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Q Well, you said that there's information in the surveillance program that you would consider if you were evaluating a product -- well, let me back this out a little bit.
You'd consider the surveillance information -- surveillance program information if you were consulting for a client in the pharmaceutical industry that said evaluate this product, right?
A I might.
Q You said earlier that you would want to see it and that you might.
A I would -- I might --
Q Are you changing your testimony now?
MR. MILLER: Object to form.
A I'm not changing my testimony. If I said I would I would.
Q Okay. And you would also want to see all of the regulatory documents that you reviewed in this case, right?
A Yes.
Q But if you were counseling plaintiffs in the context of this litigation you don't want to see the 484 information because you thought about it and chose not to ask for it.
MR. MILLER: Object to form.

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A The reason to look -- to have one sample taken and analyzed and be found good doesn't tell me after reading all of this that the firm is not making unsafe material out there to have one sample. So it wasn't anything that would have any statistical relevance to me.
Q What if it was more than one sample? What if it was part of the surveillance program year after year?
A It's tough to pick a finite number, but the answer would be yes. If it got to the point where it was a statistically representative number, then, yes.
Q Out of 152 what would be a statistically representative number?
MR. MILLER: Object to form.
A 152 what?
Q Batches.
A We would be looking at -- I'd rely on a statistician's answer for that. If you're asking for my opinion, my opinion would be I'd want a sample from every batch.
Q That's not a statistically representative number. Your term, Mr. Farley, not mine.
A Okay.
Q So when you -- what would be a

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representative sample sufficient to allow you to credit that?
MR. MILLER: Object to form, asked and answered.
MR. ANDERTON: It hasn't been asked. It hasn't been answered.
MR. MILLER: It has been asked and it has been answered.
BY MR. ANDERTON:
Q You may answer it.
A I believe I would not make that determination myself. I would ask a statistician, because the answer, I'm sure, would depend on whether it was one campaign making 150 lots straight on through one after another or whether they made 10 lots and then changed the equipment over and made something else and a few weeks later started making this material again and then stopped and start again. And that number would vary. And I would rely on the statistician for that.
Q And if it was a single campaign of 152 straight batches, according to you would the number be higher or lower than if it was multiple campaigns of four batches and five batches and then three batches?
A If it was a single campaign right on through, same equipment, same everything, I would

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believe the number would be lower --
Q Okay.
A -- than if they were disassembling the equipment, making something else, cleaning it, re-assembling for that.
Q Did you ask about any external testing of the recalled Digitek?
A Did I ask about any external testing?
Q Yes.
A External testing.
Q Yes.
A I did not. I looked for analytical results on the double thicks, but I did not ask about external testing.
Q Explain to me the significance of the analytical results on the double thick tablets. The 20 tablets out of 4.8 million, what significance would that have?
A If, and especially this with a low therefore dangerous therapeutic index where a patient can overdose very readily, if it's double thick and double weight, is it the same amount of active ingredient and twice the excipients or is it a double strength tablet, because a double strength tablet could kill someone.

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Q Okay. So your analysis would be intended to determine the potentially harmful effects of those 20 tablets?
MR. MILLER: Object to form.
A Yes. I would do that in any case as good practice because knowing the analytical results helps you determine where along the line something went wrong.
Q I understand. But the point is it would help you determine the potentially harmful effects of those 20 tablets and perhaps allow you better insight into determining the root cause.
A Yes.
Q But it doesn't affect the potency of the other -- let's call it 4.8 million tablets, because 20 out of 4.8 million leaves almost still 4.8 million.
A In theory it does and if the analytical results were all within specification by their sampling procedures, then theoretically they're all in the proper strength.
Q And those batch records you reviewed. But the double thick batch are the records you reviewed.
A Batch record, yes.
Q And no others.
A Did not see them.
Q Didn't ask for them. Didn't ask for any

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additional batches, did you?
A I asked for a batch before and a batch after.
Q Did you get it?
A No.
Q Did you ask for any batches other than the batch before and the batch after?
A I said if we can't get the one immediately before and immediately after, get me one that was sometime before, the closer the better, and sometime after, the closer the better.
Q Didn't get those.
A Didn't get them.
Q Why not?
A I don't know.
Q How many times did you ask?
A Twice.
Q What were you told when you asked and didn't get them?
A We'll get them.
Q Didn't.
A Didn't.
Q Did that affect your opinion at all?
A Of what?
Q Well, of anything in this case. I mean,

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you're giving expert testimony in the form of an opinion. You asked for information that you obviously thought might be relevant, or you wouldn't have asked for it, and didn't get it.

A I had less to work with, but I still had what I felt was a sufficient amount. I had a batch record, the batch that had the double thick tablets.

And there's -- when you do a project there's also it'd be nice to have this, nice to have this, this will be good. And some things if you don't have them you say, I can't go on without this. Others you say, I'll evaluate what I have.

Q The batch before and the batch after, if they had come in, if the records for those batches show everything within specifications how does that affect your opinion in this case?

A If that came in I will look to picture that whatever it was that went wrong that made that occurred at that particular point in time.

Q It was an isolated incident.

A I would tend to look that way, yes.

Q Okay.

MR. ANDERTON: How much time we got?

THE VIDEOGRAPHER: 25 minutes.

MR. ANDERTON: Okay.

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BY MR. ANDERTON:

Q What discussions have you had with Mr. Miller or other Plaintiffs' counsel about the theory being pursued by Plaintiffs in this litigation?

A I'm not sure what you mean by the theory.

Q Well, when you sue somebody alleging you've been injured by their product, you have to have a reason for suing them. You understand that, right?

A Yes.

Q And, you know, I suppose it's lawyer speak a little bit, but when you bring a lawsuit, until it's been proven or proved you're pursuing a theory.

You understand now what I mean when I use the term theory?

A Yes.

Q All right. So what conversations have you had with Mr. Miller or any other lawyer for the plaintiffs in this litigation about the theory of liability being pursued by the plaintiffs in this litigation and specifically as it relates to what they think was defective about the Digitek?

A I can't recall the exact words of any discussions I had, but Pete Miller would say, what did you find, what are you coming up with, and, of course, when can I expect the report or the results; although I try to get them promptly.

But I believe what I said to Pete Miller, Pete, this place is really fouled up at this time, I wouldn't trust anything coming out of it. And Pete would say, well, we're looking at that aspect of it, or something to that effect.

But I believe that I brought the subject up to him that you're talking about Digitek, but I wouldn't trust anything made in this company by these people at that time.

Q And the basis for that statement is your review of FDA regulatory documents, correct?

A Documents, the various things, a lot of different things that were -- it wasn't one violation over and over. It was different violations.

Q But all of those are set forth in FDA regulatory documents, right?

A Yes.

Q Because you didn't review any manufacturing documents for any product to reach your conclusion that this place is really fouled up, right?

A Other than that one batch record. And my conclusion was based on the various observations of the various 483s.

Q So your contention is based entirely on comments set forth in FDA in the 483s and FDA regulatory documents.

MR. MILLER: Object to form.

A Mostly. There are some of the other things we discussed, I'm sure played a role, but predominantly the FDA documents, the inspection results.

Q This industry as we talked about earlier is based on sampling of finished product, right?

A The industry is based on it?

Q Or --

A I don't know if I would use that word.

Q That's a poorly-phrased question and I apologize.

A You said it.

Q The release of product into the market in this industry is based on sampling of finished product, right?

A Yes.

Q How do you assure -- how can you be sure that all product released into the market is within specification? Is there any real way to do that?

A Is there any real way to be sure that every individual tablet and the batches? To be sure you would have to test every tablet.

Q Right.

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A You do statistically representative sampling. And you have statisticians who know where the statistical tables are. When you're making this much take a sample, take it from here, take it from there. And you do your -- we call it representative sampling. You analyze that.

Q So if somebody says, assure me every tablet in the market is within specification, is that possible?

A Not without testing every sample. Now, when you say specification, specification for weight? For size? For analysis? For everything? For everything? The right excipients? The right active ingredient? The right strength? You would test everything and you would have nothing left to sell.

Q So if somebody says, assure me that every product that you've already released into the market is within specification, that's not possible.

A In an absolute sense, no. You would base it on your sampling and your test results.

Q You'd go back to your batch records.

A Uh-huh.

Q You'd review the batch records and there would be nothing else you could do at that point, right?

A Nothing else you could do with regard to

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the answer for the person?

Q Yes.

A You say, here's our batch, here's the results, it all tested well.

Q Right. Nothing else you can do, right?

A According to your procedures nothing else you would do.

Q Nothing else you could do other than -- other than go test it all.

A Or test some more to any degree. But you likely wouldn't do that. You likely would say, here's the results that we had and this is statistical sampling; therefore the batch is released. That's what you would do.

Q Okay.

A Uh-huh.

MR. ANDERTON: Let's take a brief break.

THE VIDEOGRAPHER: We're off the record at 4:07.

(A brief recess was taken.)

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THE VIDEOGRAPHER: We're back on record. The time is 4:19.

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CROSS EXAMINATION

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BY MS. DOWNIE:

Q Mr. Farley, my name is Ericka Downie. I'm going to ask you a few questions today, this afternoon. I was looking through the records that you brought with you today and I understood that you brought with you documents that you reviewed in preparation for your -- in preparing your report as well as in preparing for your deposition today related to this litigation; is that correct?

A Yes.

Q Okay. In going through those documents I found some e-mails and some documents I wanted to question you about. Who is Hua, H-U-A?

A Hua.

Q Hua. Fair enough.

A Hua is Dr. Hua Zhao. He is a chemistry teacher at Savannah State University and I asked -- he's a friend, a fellow chemist and a neighbor. And I asked him to weigh a couple of tablets for me in the laboratory.

Q Why?

A I wanted to look at the various medications, the ratio of active ingredient, API, active pharmaceutical ingredient, to the total tablet weight and get those ratios.

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Q Why was that important information for you?

A It was important to me because when I looked at .125 milligram strength of Digoxin, the Digitek product that is .125 strength, and then I saw that the tablet weight was 105 milligrams, I calculated that out on a -- first on a percentage basis -- I see you have the chart in front of you -- on a percentage basis and then I converted to a parts per thousand, parts of active ingredient per thousand parts total tablet weight.

And I'm saying this off the top of my head. I just asked Hua to do the tablet weights of the others, the Benadryl, the Advil. I did not have the tablet weight of Digitek, but I got the tablet weight from the records. And then I calculated that for the .125 strength Digitek.

That is just over one part of active ingredient, 1.2 parts perhaps of active ingredient, to a thousand parts of total blend. And that's difficult to mix, I would believe, such a dilute mixture.

So he weighed a Benadryl, he weighed a Lipitor -- and that was right out of my prescription bottle, the Lipitor -- and an Advil. And I think you have the --

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Q And it appears -- I'm sorry -- also Diovan.
A Diovan.
Q Right. Okay. So he did these weights for you?
A He just did the tablet weights.
Q Right.
A The strengths are the claimed strengths on the labels.
Q Okay.
A And I just looked -- and I'm looking at the data upside down as you have it there --
Q Right.
A -- that when I looked and I said to myself, wow, this is 1.2 parts per million mixture of the active ingredient in the Digitek product at the.125 milligram strength, that really has to have a lot of care taken to mix it pretty thoroughly. And while the others had -- I forget. One was well over 100 --
Q Well, we have one that's 56, another that's 65, another that's 99. So three of them are under 100.
A Under? And what's the one that's --
Q Then there are two that are well over 100, the Advil and the Diovan.

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A And while you want blend uniformity in anything you mix it's, quote, unquote, it's easier to get in the Diovan or the other ingredients and it would be tougher to get in the more dilute product.
Q Did you review -- did you conduct this examination at Plaintiffs' counsel's request?
A No. In fact --
Q And did you actually have any Digitek tablets to weigh?
A No. I got that from the batch record.
Q So there weren't any Digitek tablets that were actually weighed as part of this analysis that you conducted?
MR. MILLER: Object to form.
A There weren't.
Q So, Dr. -- I'm sorry.
A Dr. Hua Zhao.
Q Dr. Zhao, he didn't weigh any Digitek; he weighed other medications for you.
A The others that you have in the bag there.
Q And you haven't reviewed any other batch records with respect to Digitek to determine anything regarding blend uniformity or content or anything of that nature for a product that was actually released and distributed on the market?

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A Did not, only that one lot in question.
Q And do you -- this looks like this analysis was done on June 11th, 2010?
A That's probably when Hua gave me the data or sometime there and I just entered it and did my calculations on the Excel spreadsheet there.
Q Approximately how many hours have you spent on this litigation?
A On the litigation total?
Q Yeah.
A I'm pausing because I'm thinking back to the billable hours.
Q If you can just give me an estimate.
A About 175.
Q And are you currently engaged by any other entities or facilities with respect to consulting? Any other consulting engagements currently?
A I just finished one. I have another pending but not actually doing it right now.
Q Okay.
MS. DOWNIE: All right. I'm going to turn the questioning back to Mr. Anderton.
MR. ANDERTON: Okay. Thank you.
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DIRECT EXAMINATION (Cont'd)

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BY MR. ANDERTON:
Q Mr. Farley, I started to ask you some questions about this earlier and then I changed course and I never finished my thoughts on this issue. So I want to follow up.
We looked at the FDA document from the Web site which indicates the FDA's thoughts that the recall of this product is -- flows from the double thick tablets found in one lot.
Would it bother you -- or does it bother you to know as you form your opinion in this case that Plaintiffs have changed their theory -- we started talking about theory earlier -- and that initially they brought claims that they were taking and had taken double thick tablets and that since then they've changed their theory to now being pursuing this notion of varying degrees of active pharmaceutical ingredients, whether the tablet is double thick or not?
MR. MILLER: Objection. Object to form, overbroad and it's facts not in evidence.
Q You may answer.
A Well, I didn't know it. Since I didn't know it it doesn't bother me.
Q Hearing it now does it bother you?
A No. My work was look at these documents,

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provide an evaluation. And I -- it would bother me if I thought people were dying taking medication, I mean, as a fellow human being. But speaking of the case, no.

Q Do you know how many lots were subject to this recall?

A The number 33 comes up and a number of 85 comes up.

Q Okay. If I told you it was 152, would you have any reason to doubt that?

A I would not have any reason to doubt that. In fact, I would relate it to the number that you mentioned earlier.

Q Okay. And if I tell you that the .125 -- the theoretical batch size of .125 is 4.8 million and the theoretical batch size of .25 is 4.2 million, do you have any reason to doubt those numbers?

A No reason to doubt them.

Q So if there's 152 batches that were subject to recall in this case, those numbers mean we're looking at north of 680 million tablets.

Does that sound about right?

A Quick calculation, sounds about right.

Q Okay. Not a single double thick tablet has been presented to Defendants in this case. Do you -- are you aware of that?

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A I was not aware of that.

Q Is that something you would have liked to have known as you formulated your opinion, as you put it, as you evaluated Digitek?

A It would have been helpful but not necessary. When I read those 483s and I saw the observations on the 483s and I read the warning letters to -- now to answer with that knowledge after reading that to answer your question, oh, it wouldn't matter.

Q The 483s would do nothing but prompt you to look further, right?

A It would prompt me to look further because I see violations and I want to know why don't they correct them, are they going to correct them, which is what FDA wants to know.

Q Okay. And they would prompt you to -- if you're evaluating Digitek and if you're doing it properly, you'd take the information you learned in the 483 and you'd evaluate information reflecting the manufacturer of Digitek, right?

A Yes, but I'm taking the FDA's word for what they put in the 483. I'm not --

Q You still have to connect --

MR. MILLER: Hang on. He's answering. You're cutting him off.

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Q Go ahead and answer.

A I'm not looking for supplemental information because I doubt the FDA's content of the 483 or the warning letter. But any supplemental information is always helpful.

Q Well, you still have to connect the information on the FDA's documents to Digitek, right?

A Oh, yes. In some cases they mention it and other cases they mention other products.

Q And in the cases where they don't mention Digitek, as you said earlier, you have to connect that specific citation to Digitek --

MR. MILLER: Object to form.

Q -- somehow.

MR. MILLER: Misstates previous testimony.

A I'm looking to evaluate the whole firm and Digitek, but I'm not looking to say how can I get this to make it look bad for Digitek. No, I'm not. Maybe I'm not getting the question right.

Q Yeah. Let me try to say it differently. Let's separate your evaluation of the firm from your evaluation of Digitek. All right?

MR. MILLER: Object to form.

Q So I don't want to hear in my response to

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this question about your evaluation of the firm. As you're evaluating Digitek and forming an opinion about Digitek, if you find a reference on a FDA form to a -- what the inspector believes is a GMP deficiency, in order to evaluate Digitek, as you testified earlier, you have to go look for information about Digitek, right?

MR. MILLER: Object to form.

A Yes, but I would also look for more information about how they're making other things if it's in the same plant by the same people. I would do what you say first, but not only, because although you said to me separate Digitek from the firm, I can try to do it but there's overlap. There's overlap.

It's the firm that makes the Digitek. It's the same firm that made these products that's making the Digitek. So I know you said to me separate it, but I can't completely separate it.

Q Is it your opinion that if a firm makes one product defectively they make all products defectively?

A No. It's my opinion that there is a possibility that some other products are being made defectively.

Q But you can't confirm unless you look at records, right?

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A That's right.
Q You know about batch yields, right?
A Yes.
Q Are you -- a theoretical yield is the number of tablets that should be produced in a typical batch if tablets are manufactured within specification, correct?
A Yes.
Q If batches contained double thick tablets, that would potentially impact the yield of the batch, right?
A Of the number of tablets, yes.
Q Something you could examine as part of your evaluation of Digitek?
A Yes.
Q You didn't do that, did you?
A For the number of tablets, 15 out of 4.8 million, the yield would not have given me an indication either way.
Q It wouldn't be because 15 or even 20 is in fact I think the real number, 20 out of 4.8 million would not have affected the yield.
A The yield as in the specifications. I forget the number offhand, but if it's so many kilograms put in and 98 to 102 percent and it came out, you

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wouldn't see it by looking in that area.
Q Okay. But you didn't look at any yield for any batches other than the double thick batch?
A And that was in reviewing the whole batch record I saw you go through.
Q So as I understand that comment, you saw the yield but not because you were looking for the yield. You just were reviewing the batch record and it was in there.
A It's one of those things where you're looking at an aspect of something and you want to look at other parameters. Which parameters do you look at that will give you information that will help you explain this situation? And I don't think that would give me any information.
Q Are you familiar with Quantic Regulatory Services, Quantic?
A Am I familiar with it. I've done work for them.
Q You have done work for them?
A Sure.
Q Are you aware that they -- at the request of the FDA that Actavis hired Quantic to undertake a review of various batch records and documents?
A Quantic is good on that. I've done batch

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reviews for them on other projects, other clients.
Q You trust their results?
A I trust Quantic's results.
THE VIDEOGRAPHER: I have to change tape now.
MR. ANDERTON: Okay.
THE VIDEOGRAPHER: Off at 4:35. One moment, please.
(Off the record.)
THE VIDEOGRAPHER: Okay. This is the beginning of Tape No. 7. It is 4:36 p.m.
BY MR. ANDERTON:
Q Mr. Farley, before we changed tapes I asked you a question about Quantic Regulatory Services. You indicated that -- there were several questions. You indicated you're familiar with them, you've worked with them and for them and that you trust them.
Is that a fair characterization?
A Yes, to all.
Q Okay. But you didn't answer the question I asked you originally which was, were you aware that Actavis hired Quantic to undertake an audit review of batch records at the request of the FDA in 2007?
A Not the way you say it. I saw Claudio Pincus' name and Owen Richards' name. And Claudio

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Pincus and Owen Richards are Quantic. They own it. And so I knew they were involved because I saw their name on correspondence or they were cc'd on some e-mail. So I realized that. And I also saw PAREXEL, which is a competing firm. So that's how I knew.
Q Did you ask for any documents relating to Quantic's involvement?
A No, I did not.
Q You trust them. You knew they were involved. You didn't ask to see what they had done or what the results were?
A I didn't need to. If Claudio has a team in there doing a job, they're doing a good job. I did that type of work for him on various projects.
Q I'm not asking if you asked to see Quantic's documents because I'm asking you to second guess their results. I'm asking you whether you thought that was potentially relevant to your evaluation of the firm.
If Quantic did a good job, as you've now said multiple times --
A Yes.
Q -- wouldn't you want to see their outcome as part of your evaluation of the company?
MR. MILLER: Object to form.

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A I want to see the immediate FDA inspection that follows Claudio's implementation of the results to verify that what he did, and which I have explicit trust, has been put to use satisfactory.

So I don't need to see what Claudio's doing -- or I should say Quantic was doing. I want to see the FDA inspection, because they're the ones that are going to say you can now market it or you can't market it. So that's why I didn't ask to see it. And this moment I still don't care to see it.

Q What's a compliance hold? Do you know?

A You're holding something until something else is done and then you will release it when that something else is done. That's obviously not the FDA definition.

Q What's the FDA definition of a compliance hold?

A I gave you mine because I was vague on their words. That's why I gave you mine.

Q Okay. Let me ask it a different way. When a company has been issued a warning letter -- and I'll characterize that as being under or subject to a warning letter -- is the company -- is the FDA going to grant new product approvals while that is the case?

A In a warning letter?

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Q Yes.

A That would depend on the content of the warning letter, the scope of the warning letter and what else was needed. If it all centered in one location -- I mean same company, one location, and there was never any problem with another location of the same company and the warning letter applied here, they may let them produce here.

Q At the other location.

A Yes.

Q What if it's all one location?

A Here again we get into that it is quite likely not, but in certain instances of a product that is needed in the market, when you have someone who is primary supplier and the shortage of that product on the market would be harmful to people who need the medication, they will -- I don't know how to put -- work with the company, but put that in quotes, work with the company in trying to help them get the product to market. So it will be a warning letter --

Q Are you talking about a product that's already been approved?

A Yes.

Q Okay. I asked you about new approvals.

A New approvals.

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Q Yes. Will the FDA grant new product approvals while a company is under a warning letter?

A Quite likely not but in theory they could.

Q In your experience have you ever seen that happen?

A No.

Q You were -- were you told by Plaintiffs' lawyers in this -- as you were preparing your report for this litigation that after the 2007 inspection that we talked about earlier eight to ten new product approvals were granted by the FDA to Actavis Totowa within two months after that?

A No, I don't recall that.

Q Were you told by the plaintiffs' lawyers that the outcome of that inspection is that the warning letter that had been in effect since early 2007 was lifted?

A I wasn't told. I have information that I've been reviewing.

Q And you saw the outcome of that 2007 inspection was VAI, correct --

A Yes.

Q -- voluntary actions indicated?

A Yes.

Q So if Quantic did a review of Digitek

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batch records as part of a project for which they were hired by Actavis in 2007 and that review included recalled batches, that's of no interest to you in evaluating Digitek?

A It's of interest to me, but what is more interest is what the FDA says. Quantic is coming in to fix it and if someone comes in and says, hey, that's great, they can market it, I want to see what the FDA says, because the FDA is the regulatory body. Quantic isn't.

Q Quantic is not coming in to fix it. They're coming in to review what had already been released.

A They do both and I wasn't sure what they did here.

Q Well, what they did here was review what had already been released. So let me start that over a little bit.

If Quantic came in and reviewed batch records for Digitek that had been released to market to determine compliance, is that something you'd want to see as you evaluate Digitek?

MR. MILLER: Objection, asked and answered.

A It would be helpful to see, but I want to

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see what the FDA says. We keep coming back to this.
Q But Quantic was hired at the request of the FDA and the results were submitted to the FDA. Would that be of significance to you?
MR. MILLER: Objection, asked and answered.
MR. ANDERTON: It hasn't been asked and answered, Pete. Not close to asked and answered.
A I thought it was. So I guess I better -- let me think. It would be of interest to me, but it wouldn't be absolutely necessary. I read a series of 483s and a couple of warning letters and I have a very low opinion of the capabilities of the company.
Q Based on that review of those 483s --
A Those several 483s --
Q -- and the warning letter.
A -- and the various EIRs. And if a company like Quantic is coming in to review the batch records, I say fine. And if you say what's the company look like, let me see the latest thing from FDA that says they're good again.
But -- so that's why I don't think that I miss what they -- I know they're good. I know what they do. And they do in some cases help prepare, actually put people in position.

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And -- but I didn't have to see that. It won't change my judgment of what was and what needs to be to have a quality product on the market.
Q Let's turn to your report. Again my copy has disappeared. Will you turn to page 17, Mr. Farley?
A I am at 17.
Q What is the purpose of the comments section of this report?
A My comments -- I didn't know who all was going to read this, how familiar the people would be with the pharmaceutical industry.
And in this regard I do remember I asked Peter Miller, I said, in doing my report I don't know the whole readership of this and I would like to put in a comments section that's going to maybe make it a little more worthy, but I feel it will explain things.
And the reply was something to the effect of, whatever tells the story when in doubt. So I requested the okay to put a comments section in for the reason I just mentioned.
Q Okay. So those aren't part of your official expert opinions in this case. They're background information that you feel helps tell the story and allows the reader who might not have FDA experience to have a better understanding of the

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opinions you've offered which are in the conclusion section.
MR. MILLER: Object to form, misstates previous testimony.
A I got lost somewhere in that question.
MR. ANDERTON: Will you please read that back and read it relatively slow so that I can understand it as well. I need it slow.
(The record was read back as requested.)
A There are facts and opinions in here. I do some quotes, which, of course, are facts. And then I'm looking to see where -- well, just statements. Recalls are actions taken by a firm. I'm reading D. What I am doing is exploring that are these my opinions. I'm looking to see if I have opinions in here.
Q So I think your testimony is that you do have opinions in your comments section.
A I'm looking here where I have that total failure thing again. When I say to have a total failure such as this indicates there's no product of this company at that location that can be relied on, that's my opinion. I'm sure it's shared by many, many, many people that I work with. But you could classify that as an opinion.
Q Okay. So let's work our way through these

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then. That Paragraph A on page 17, it's accurate to say that that's based entirely on that -- the notes of that close-out meeting, correct?
MR. MILLER: Objection, asked and answered.
A Based on that three- or four-page --
Q Yes.
A -- correspondence that we saw? I saw somewhere else somewhere Robert Wessman and agreement. Other than that I just can't remember it now, so --
Q Well, you've indicated here that you're quoting Plaintiffs' Exhibit 106.
A I am.
Q And you're not referring to any other document and you're using quotes.
A I did in there, right. Yes. Everything you said is correct.
Q So this paragraph refers exclusively to Plaintiffs' Exhibit 106?
A But I saw Wessman's name somewhere else and I'm just not clicking whether I relate it to this. But predominantly that three- or four-page correspondence, unsigned and undated on Actavis letterhead.
Q Well, how can -- Mr. Farley, let's not

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throw common sense out the window. Okay?
A Right.
MR. MILLER: Object to form.
Q In the first sentence here you refer exclusively to Plaintiffs' Exhibit 106. And the rest of the text until your opinion is in quotes.
MR. MILLER: Is that a question?
A What is -- I don't understand the question.
Q So how can it not be true that that paragraph and that opinion is based entirely instead of just predominantly on Plaintiffs' Exhibit 106 when you refer to it and then quote exclusively from it?
A It quite likely is exclusively from it, but I remember reading the name Wessman somewhere else. And I may have incorporated some of that in there, if in fact I'm correct.
Q So you may have incorporated some of that in there even though you refer to a document and then go on to quote from it twice. So the reader is supposed to understand that the next comment actually incorporate -- and then in the next sentence you go back and quote from it again, to have a total failure.
Do you see that?
A Yes.

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Q Okay. That's another quote from Plaintiffs' Exhibit 106.
A From Plaintiffs' 106.
Q So the reader is supposed to be able to understand that you've actually, perhaps implicitly, but without giving anything that would indicate such worked information from another document into that comment?
MR. MILLER: Object to form.
A I did not work information from another document into that.
Q Okay. Then my question stands. Is it accurate to say that the comment in Paragraph A is based entirely on Plaintiffs' Exhibit 106?
A To the best of my knowledge, yes.
Q Okay. Now, this total failure comment that is in the Plaintiffs' Exhibit 106 which we talked about earlier, it doesn't appear in an EIR, does it?
A It appears in -- well, the Actavis document is quoting from what, the lady's name, Erin, the inspector, either wrote or said.
Q My question is, does it appear in an EIR?
A I don't remember if it's written or said.
Q Wouldn't you have cited and quoted that if it appeared in an EIR? I mean, that's a little more official than scribed notes, right?

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MR. MILLER: Object to form.
A I may or may not have.
Q Total failure would be the opinion of the investigator, right?
A Since Actavis -- go ahead.
Q Total failure would be the opinion of the investigator, right?
A Yes. And I think I read that somewhere.
Q You did, in Plaintiffs' Exhibit 106 to the extent it's accurate.
A I believe that whoever wrote that was referring to what Erin, the inspector, said to him or her.
Q Okay. But I'm now -- I'm simply trying to ask you, Mr. Farley, and if you just pay very close attention --
A I'm trying.
Q -- I'm trying to ask you whether it appears in another document. That's not that difficult a question, yet you're so intent on not conceding this that you're just ignoring my question and answering whatever question you want.
A Can I see Plaintiffs' 106?
Q Can you see it?
A Yeah.

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Q You absolutely may. You absolutely may.
A I can't find Plaintiffs' 106. I've got a big pile here. Let me look through my pile. 106, page 1, whoever the author was is referring to Erin McCaffery and seems to be quoting -- she puts total failure in quotes -- leading me to believe that Erin McCaffery said or wrote it.
Q Now, my question is, that total failure comment doesn't appear in an EIR, does it?
A I don't remember if it's in an EIR.
Q Well, the document will speak for itself.
A Yes.
Q But it either does or it doesn't, right?
A It either does or doesn't.
Q And that would be the opinion of the investigator, right?
A She would be reflecting an opinion based on facts that she observed.
Q So it wouldn't belong in an EIR if it's there, right?
A They're not supposed to put opinions. You're not supposed to put opinions on 483s. You're supposed to put facts on 483s and you're only supposed to put facts on EIRs also.
Q So it doesn't belong in either an EIR or a

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483.
MR. MILLER: Object to form.
A That is correct.
Q And in fact, it doesn't appear in either the EIR or the 483, does it?
A I don't -- apparently Erin McCaffery either wrote it or said it, because she's being quoted. That's why I put the single quotes in there.
Q Okay. In Comment A you refer to products with no impurity profile. Do you see that?
A 48 products with no impurity profile.
Q Was Digitek one of those products?
A Don't know.
Q You didn't review any batch records to find out, did you?
A Did not have to.
Q You didn't review any batch records to find out, did you?
A Correct.
MR. MILLER: Objection.
Q Paragraph B --
A Yes.
Q -- you quote from a complaint for permanent injunction and then you offer a comment. Now, you authored an article with lawyers. I assume you've

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been around enough to know, and you worked for FDA for eight years, you know a complaint is nothing but allegations, right?
MR. MILLER: Object to form, calls for a legal conclusion.
A I'm thinking of that. The way you have it worded I'd say it's an allegation.
Q Allegations are -- statements in a complaint are allegations, right?
A Yes.
Q Untested, unproved.
MR. MILLER: Object to form.
A Yes.
Q Your comment in Paragraph B, this leads any responsible person to ask why didn't they fix what was broken.
A Yes.
Q Did one of Plaintiffs' lawyers suggest that things were broken at Actavis to you?
A No.
Q Did you ever talk to a gentleman named Ed Blizzard?
A No. I've read that name in depositions.
Q Okay.
A He's an attorney?

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Q He is an attorney.
A I've never spoken to or met the gentleman.
Q Okay. We spent a lot of time going through the EIR for the 2007 inspection. Do you remember that?
A Yes.
Q Fifteen observations. Every one Actavis proposed and implemented corrective actions in response to every one. Do you remember that?
A I don't remember implementing them. What I saw was, here's what we're going to do, here's what we're going to do here, here's what we're going to do, we hire this many people.
And then I was trying to say time will tell if it works out if they really do it. But at that instant in time that's what they proposed.
Q Okay. Mr. Farley --
A We had a difference there.
Q Mr. Farley, it isn't what they proposed; it's what they did. There's a difference between doing and your notion of time will tell whether it is the absolute effective solution.
You understand that, right?
MR. MILLER: Object to form, argumentative.

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A State your two points, now.
Q You understand that, right, that there's a difference --
A Yes, I do.
Q Okay. And if we have to go back through that again and convene for another day of deposition, I'm happy to do that.
A Fine.
Q The record will show what it shows.
A Yes.
Q But in fact, the EIR shows 15 observations, 15 sets of corrective actions actually taken by Actavis, doesn't it?
A Taken, started at that time.
Q Yes.
A Yes.
Q None of them indicated by -- nowhere does the FDA indicate that additional corrective actions are necessary.
A Not if they work out.
Q Well, but the FDA is saying no corrective actions are necessary. You gave that testimony in response to all 15. You're not going to go back on that, are you?
MR. MILLER: Object to form.

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A I'm not.
MR. MILLER: Misstates previous testimony.
A But the FDA is also saying back at their district office, let's get the calendar and look when we're going to inspect them to make sure those corrections work out.
Q Okay.
A That's the point that I'm trying to make.
Q And I'm not suggesting that they are absolved of compliance on all those issues forever.
A Yes.
Q I merely want to explore the notion of whether corrective actions were taken.
A They were.
Q Absolutely were.
A We agreed on that step by step, every one.
Q All the way through.
A Sure.
Q Go to Paragraph C.
A I'm there.
Q It's not true that companies hire third parties only when they can't achieve compliance by themselves, is it?
A You say it's not true?

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Q Yeah.
A Correct. It is not true. They hire third parties to help them out whenever they feel they need them, not necessarily when they have a problem.
Q Okay. And sometimes they hire them just because maybe they want to expedite something and they don't necessarily have the resources themselves to do it and they want some assistance making sure something happens within a time frame that they need to accomplish, correct?
A Yes.
Q Have you ever been hired for that purpose?
A Yes.
Q How many times?
A A few times every year for a variety of things, reviewing internal documents, evaluating a contract manufacturer or contract packager. It varies as to what they need you for.
Q Okay. And you also can hire a GMP expert to evaluate your methods and facilities and controls just because you want to conduct some sort of evaluation, correct?
A Yes.
Q And that happens?
A Yes.

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Q So it's not true that that happens only in the context of a consent decree.
A Correct.
Q You're aware that all of the other products made by Actavis Totowa other than Digitek were recalled at some point during 2008, right?
A Yes.
Q Are you aware that was not a consumer level recall?
A Yes.
Q Patients were instructed to continue taking those products?
A Yes.
Q By the FDA.
A Yes.
Q Why would the FDA do that?
A Were permitted to by the FDA, I would say.
Q Well --
A If you want to say instructed, I'm saying permitted.
Q Press releases announcing recalls are submitted and approved by the FDA, correct?
A You're not talking about these unsigned things that you saw on the Web that you showed me?
Q No. I'm talking about the official press

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release --
A Official press release?
Q -- where a recall is announced.
A Yes.
Q Submitted to and approved by the FDA, right?
A Yes.
Q So the press release -- the press release that announced the recall of the products other than Digitek was submitted to and approved by the FDA?
A Yes.
Q Had to be.
A Oh, yes.
Q So it told consumers to continue taking all those products submitted to and approved by the FDA, right?
A Yes. That took a minute, but then it kicked in to my memory.
Q Okay. Let's go back to this comment about -- you keep wanting to say that sometimes the FDA will let a product go to market if it's necessary.
What's the basis for that statement?
A Let's say that a particular firm, Firm A, makes a product and it has 80 percent of the market of that product. But Firm A now encounters a problem with

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that.
But if Firm A were to be shut down there would be patients who couldn't get the product because the only other firm that makes it doesn't make enough of it and can't get gear's up to do it.
So the FDA will then come. And remember I said put work with in quotes. They'll work with them in giving them more guidance in how can we approve things to get them out to the people who need it. That's what I was referring to. They're rare cases indeed, but they do happen.
Q Well -- and ultimately the only thing that really matters is GMP compliance, right?
A That's right.
Q So it doesn't matter whether the product is important or not. If you don't have GMP compliance it's not going to market.
A That's correct.
Q Now, you keep -- or you've referred several times and I believe earlier you actually said an observation you use interchangeably with a violation on a 483.
A In conversation I use it interchangeably.
Q Okay. I guess that's a qualification on your earlier testimony then. So I need to make clear.

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And we talked about this a little bit earlier.
An observation on a 483 is not -- is not even intended to reflect an actual violation. It's just the observation of the inspector about some condition that they want to see changed.
A That they want to see changed because it's violative.
Q Well, will you look at your report on page 18, Mr. Farley.
A Page 18?
Q Yeah.
A I'm there.
Q And you, in Paragraph E on the Fact versus Opinion --
A Yes.
Q -- you quote the Investigations Operations Manual, Section 5.2.3.3 as reading, Do not -- quote, Do not report opinions, conclusions or characterize conditions as violative. The determination of whether any condition is violative is an agency decision made after considering all circumstances, facts and evidence.
Do you see that?
A I see it.
Q Did I read that correctly?
A You read it correctly.

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Q I have the section here as an exhibit, but do you believe you accurately quoted that --
A I believe I accurately quoted that.
Q -- operations manual? So the operations manual tells inspectors, whatever you write don't indicate it as a violation, we'll do that after the -- somewhere down the line, right?
A Say that again.
Q The operations manual is saying here to inspectors, whatever you write don't indicate it as a violation, we'll figure out whether it's a violation later.
A I have to explain what that means.
Q What what means?
A What that means, they determine as violative.
Q It means that they haven't made a determination as to whether it's a violation.
MR. MILLER: Are you testifying for him?
A It's, it's the way the system is set up. The inspectors come back from an inspection along with the scientists. The scientists go to the lab visiting the inspectors periodically to help with the report.
The compliance division, which is -- exists as another division within the district, their

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responsibility is to determine the classification. Is it NAI, no action indicated; is it VAI; is it OAI, official action indicated? It's their area.
So in not treading into their work area it's essentially, you do the inspection, you make your observations. They don't doubt them. They just say, make your observations. But then it comes to this area to look at it and determine whether it's a NAI, VAI or OAI.
Q This doesn't say anything about NAI, VAI or OAI, does it?
A But the violative status that -- it's just a matter of responsibilities. We will over here determine if it's violative. You wrote it, you know it, anybody that reads it knows it, but over here we are the ones who officially make it violative.
Q And until you get over here where you make that official determination it's not violative.
A And over here is right across the hall. It would be like right over there.
Q I understand, but that happens after the 483 is issued.
A Legally that's the process. In the regulatory system that's the process.
Q So yes. The answer is yes.

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A Yes.
Q It happens after the 483 is issued.
A Yes. Everybody knows it's going to be, but it isn't official until it goes across the hall and they do it.
Q Paragraph F.
A Yes.
Q When you use the term systemic -- well, when you say in the last sentence there all products, including Digitek, were adulterated -- you see that --
A Yes.
Q -- did you -- you didn't review any Digitek batch records to reach that conclusion.
A I reviewed one Digitek batch record, but that did not come into this conclusion.
Q Well, this conclusion flows exclusively from FDA documents.
A Yes. In fact, it's not in the conclusion section. It's in the comments section.
Q This comment flows exclusively from your review of FDA documents. You took the FDA at their word.
A Yes.
Q You didn't do anything to follow up and specifically determine whether Digitek was adulterated.

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A Looking at failure to -- when you're not manufacturing in compliance with GMPs, by definition in the Act it's adulterated.
Q You didn't do anything to follow up and find out whether Digitek other than Batch 70924 --
MR. MILLER: Object to form.
Q -- had not been -- had been manufactured not in compliance with GMPs.
MR. MILLER: Object to form, misstates previous testimony.
A I didn't do anything beyond all the other 483 -- reading the 483s and -- well, I was looking for everything in there, not just for Digitek.
Q I understand that. But we talked earlier about what you do when you find that situation and you want to associate it with a specific product, you go look at the records for that product. You didn't do that.
A The way you have worded the question, no, I didn't do that. I looked at the batch record for that one lot.
Q Blend Uniformity, Paragraph G.
A Yes.
Q You talk about the products that were temporarily discontinued due to blend uniformity and/or

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content uniformity issues.
Do you see that?
A I see it.
Q Was Digitek one of those products?
A I just don't recall offhand. Perhaps I should, but I just don't recall offhand.
Q Okay. Well, don't you think you would have said that if it was in your comment?
A I may or may not.
Q Did you see any Digitek batch records that indicated out of specification results for content uniformity for Digitek?
A I don't believe I saw any of them, but I do believe I saw someone questioning blend uniformity. And it was correspondence between two individuals, but with 93 documents I'm at a loss to tell you.
Q So the answer to my content uniformity question is, no, you didn't see any documents questioning the -- or indicating out of specification results for content uniformity for Digitek.
A Not indicating. There was someone questioned it.
Q Content uniformity or blend uniformity?
A Content. There was content uniformity and blend uniformity somewhere in all those documents. But

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I -- your question was did I see any. No.
Q Blend uniformity actually isn't required for all products in the market, is it?
A Could you explain that answer, blend uniformity determination?
Q What?
A Blend uniformity determination -- blend uniformity is required.
Q Blend uniformity testing isn't required for all products in the market, is it?
A You would not need it for a liquid injectable. Your sampling procedure would take care of that.
Q The FDA will allow companies to not test for blend uniformity in certain circumstances; isn't that correct?
A They won't allow them to not test for it, but your question is blend uniformity is the way I heard it.
Q I said -- I revised my question, Mr. Farley, to ask --
A Oh. You revised the question.
Q -- blend uniformity testing is not required for all products in this market, correct?
A Correct.

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Q Including things other than liquids, correct?
A Correct.
Q So there are solid oral dose tablets that are dry blends --
A Yes.
Q -- where the FDA allows companies to not test for blend uniformity, correct?
A Yes.
Q And will you look at Defendants' Exhibit 58? It is the 2008 483.
A I'm looking through. Didn't get it yet.
Q Perhaps Mr. Miller can lend some assistance.
MR. MILLER: You're getting hotter.
THE WITNESS: What's the exhibit number?
MR. MILLER: It's in that pile right here.
THE WITNESS: Which exhibit number is it?
MR. ANDERTON: 58.
MR. MILLER: No, the next one. It should be this one here. Is that 2008?
THE WITNESS: May of 2008, Erin McCaffery?
MR. ANDERTON: Yes.

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THE WITNESS: I've got it.
BY MR. ANDERTON:
Q Turn to page -- well, I can't read the number myself. Let's call it 6. And the number down in the bottom right corner should be 28230.
Do you see that? It's cut off. The zero is cut off.
A Yes. The zero is cut off. It contains primarily Observation 4 --
Q Correct.
A -- and part of Observation 3.
Q Correct.
A I've got it.
Q Do you see Observation 4a refers to blend uniformity and particularly Digitek?
A Yes.
Q And I'm going to read that out loud. It says, Although three out of specification results -- and I'm going to skip the batch numbers, but -- Although three out of specification results were obtained for blend uniformity at the right top sample location for Digoxin tablets .125 milligrams -- and then it has the lots which I'm skipping -- on February 20, March 14 -- February 20, 2007, March 14, 2007, and September 29, 2007, no manufacturing investigations were conducted.

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Did I read that correctly?
A Yes.
Q So the issue the FDA has here is not that there were out of specification results for blend uniformity, it's that there were no manufacturing investigations conducted.
MR. MILLER: Object to form. The document speaks for itself.
A It says three out of specification -- the very first line.
Q That's what happened. But the reason the FDA cites this fact, or these facts, is not because there happen to be three out of specification results. It's because they didn't conduct manufacturing investigations.
MR. MILLER: Object to form.
A The way this is written they didn't perform under the Corrective Action/Preventive Action program and investigate these results as they should have.
Q Right. So the problem, if you want to call it a problem, that resulted in this observation is not the mere fact that there were out of specification results, correct?
MR. MILLER: Object to form. The

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document speaks for itself.
A It says although they were obtained you didn't look at them.
Q Okay. So the FDA is not taking any issue with -- I'm trying to establish something, Mr. Farley. And you're an expert in this field. You counsel clients on reading these documents.
A Yes.
Q And you charge them a nice handsome fee to do that.
A Comfortable.
Q The issue that resulted in this observation is not the mere fact that there was an out of specification result three times in blending Digoxin, correct?
A Yes, yes.
Q All right. And this next sentence, Additional samples were used to retest the blend and were reported.
Do you know whether that's called for by the relevant SOP?
A I would think it would have to be where in the blend you were doing it, what time of the blend you were doing it. If you were nearly ready to take the blend and press out the tablets that's one thing.

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If it's an intermediate sample, like just say a 30-minute mix, take one sample after 15 minutes and you should be in this range, then you'd have to write your specifications, your SOPs in accordance with that part of the process.
Q Mr. Farley, please --
A I'm trying.
Q Do you know whether the SOP for blend uniformity testing allows retesting of sample -- of extra samples taken?
A I do not know what their SOP says.
Q Did you review their SOP?
A I do not remember seeing it.
Q Did you see any SOPs from Actavis?
A I don't -- if I did it's only a few, but I don't remember any.
Q Okay. So you rendered an expert opinion about the GMP compliance status of Actavis and didn't review a single SOP.
A To my knowledge I didn't review the SOPs.
Q Didn't ask for them either.
A I relied on what the FDA said. The FDA said you're not in compliance with your SOPs, the ones you have.
Q How was Digitek adulterated?

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A By not being manufactured in accordance with GMPs.
Q Which GMPs?
A Which? 21 CFR 211.
Q All of them.
A No. That's the set.
Q Which of those was Digitek not manufactured in compliance with?
MR. MILLER: Take your time. If you need to go through all the documents we'll get all the documents.
Q Absolutely right.
A This is --
MR. MILLER: If you need help with the documents, like he just said, I'll help with the documents. We'll get them all out and you can go right down the list.
A I mean, I know I can come up with the answer. I'm just trying to think and give you the answer of the correct one, of course.
MR. MILLER: Well, it's not a memory test. We can go through each and every --
A The primary one, the one that jumps to mind, is the Corrective Action/Preventive Action, not looking at out of specification results as thoroughly --

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MR. ANDERTON: Pete, what are you doing?
MR. MILLER: I'm helping him. You asked me a minute ago to help him with documents. I'm helping him with documents.
MR. ANDERTON: Pete, we work with exhibits in this context. You don't just sit down in front of a witness and start randomly putting documents --
MR. MILLER: I'm not randomly doing anything. He brought documents at your request today. These are documents that he brought at your request today and now he's trying to answer your question.
MR. ANDERTON: I asked him a question. He's trying to answer it. If he wants to review documents he'll let me know, Pete.
MR. MILLER: Well, I'm objecting --
MR. ANDERTON: Put the binder away.
MR. MILLER: It requires --
MR. ANDERTON: Put the binder away.
MR. MILLER: I'm not putting the binder away. If the man wants to look at the binder --
MR. ANDERTON: I'm going to reach across the table -- Pete.
MR. MILLER: He's going to reach over and

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grab it and if you need it to answer the question you ask for it and he'll give it right back to you. Watch how this works.
BY MR. ANDERTON:
Q Mr. Farley --
MR. MILLER: Would you like to see the binder, Mr. Farley, to answer the question to be fair?
THE WITNESS: I'm not sure, but I didn't touch the binder.
MR. MILLER: Well, it doesn't matter who touches the binder. You just answer the question.
THE WITNESS: I want to think about it for a minute. I want to hear the question again and I want to think about my answer and then maybe I'll ask to see some documents.
BY MR. ANDERTON:
Q Okay. How was Digitek adulterated?
A And my answer was generally not being manufactured in compliance with GMPs. And then I think you said specifically point out the instances.
Q Well, let me ask it a different way, or another question. Never mind. You use -- if you'll turn to page 19 of your report, first conclusion.
A I'm on 19.

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Q And you -- the last sentence you talk about deviation -- or I'm sorry -- you talk about violations and then you go on to say in the last sentence, All of these are shown to recur, thereby indicating that no corrective actions were made.
Did I read that last sentence correctly?
A I'm looking for where --
MR. MILLER: Which paragraph?
Q Page 19, the first conclusion.
MR. MILLER: Thank you.
Q I apologize.
A I'm going to read the paragraph to myself.
Q Take your time.
A I've read it.
Q Okay. The last sentence -- in the first sentence you talk about -- I'm sorry. In the second sentence you talk about violations. And then in the end of the paragraph you say all of these, all of these, are shown to recur, thereby indicating that no corrective actions were made.
Did I read that last sentence correctly?
A Yes.
Q So it's your testimony that every single violation recurred.
A That is what I concluded after reading

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District Director Douglas Ellsworth's warning letter.
Q Every single one?
A He says -- I conclude that from it. He says these -- he mentions in the warning letter such and such and these continue to recur, you have made no effort to -- I forget the exact wording, but we can get it and I can tell you. But he says they're recurring.
Q What warning letter are you referring to? There's no warning letter after the 2008 inspection.
A No. Douglas Ellsworth's warning letter. 98 documents, I just --
MR. MILLER: This paragraph doesn't mention the 2008 inspection.
A This paragraph refers to my overall conclusion --
Q Okay.
A -- of the company itself. I'm not directing that to any inspection. But the recurrence is what I read plus what -- and I don't know Douglas Ellsworth. I'm just mentioning his name because he's the district director.
Q Okay. The last sentence where you say, no corrective actions were made, our discussion of the 2007 inspection and EIR shows that that's simply not accurate, doesn't it?

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A It -- my interpretation, if the corrective actions worked you wouldn't have a recurrence of the problem. So therefore, they didn't work.
Q So we are talking about 2008.
MR. MILLER: Object to form, misstating previous testimony.
MR. ANDERTON: No, Pete. This is in forward. It's the calendar.
Q If you are assessing whether the corrections in the 2007 inspection worked you've got to go forward, right?
A Yes.
Q That would lead us into 2008.
A Yes.
Q So there was no warning letter after the 2008 inspection.
A I'm trying to think of the date of the last warning letter. And your question was?
Q So we're talking about 2008. If your -- your use of the term recur means you're talking about 2008, right?
A Yes.
Q That was three minutes of too much work.
A I just want to make sure that I'm giving you the right answer --

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Q I understand.
A -- for everyone's sake.
Q And if it's recurred -- you understand the difference between recur and continue?
A Yes.
Q So if it's recurred that means it's happening again, not --
A Yes.
Q -- continued to happen since the last time.
A Yes.
Q So it isn't true to say that something that recurs means no corrective action was made. I can correct something and if it happens again it happens again.
A You try corrective actions and at some point in time they didn't work.
Q At some point in time it happened again.
A Yes.
Q That doesn't mean no corrective actions were made, does it?
A They weren't effective. They didn't last. I'm --
Q How do you know -- how do you know that the violation or the circumstance didn't occur for a

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different reason?
MR. MILLER: Object to form, asked and answered.
A Some of them are the same. They're almost word for word the same infraction, the same reasoning.
Q All based on your review of the FDA documents?
A Of the whole 93 documents, many of which were --
Q None of which were production records for any product manufactured by Actavis, correct?
A One was the batch record.
Q The single batch record of one lot.
A That exception.
Q Okay. With that exception of that single batch, none of which were production records, correct?
A Correct.
Q Do you know when Digitek was recalled?
A I read it in the data. I'm at a loss offhand for the exact date.
Q If I say April 28th -- I'm sorry -- April 25, 2008, do you have any reason to dispute that?
A I have no reason to dispute that.
Q Does that sound about right, April 25?
A Sounds about right.

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Q Okay. Do you know when the inspection ended?
A May of '08. Is that the one you're referring to?
Q Yes, May 20 of '08.
A Yes.
Q Turn to the last conclusion in your report.
A The very top of page 20 above my signature?
Q Correct.
A I have it.
Q It reads, Patients have no assurance of the proper quality of the Actavis products since they were produced under non-compliant conditions in violation of FDA regulation.
A Yes.
MR. MILLER: You left out the word many.
Q I apologize. Since many were produced under non-compliant conditions in violation of FDA regulations.
With that correction did I read that correctly?
A Yes, you did.
Q Which many?

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A Which many?
Q Yeah. Which products?
A Whatever were produced in that plant during that time period. And I don't know all the production records as to what was made during that time. They were in a period of being non-compliant.
And I'm saying whatever they made during that time when their quality system was not functioning -- Erin McCaffery said total failure; I'm saying not functioning well -- that you can't trust the quality of any product that was made during that time.
Q Why did you say many and not all?
A All would have been a very, very inclusive term and I didn't really know that it was all.
Q You just --
A So I put many.
Q So you don't really know that it's all.
A I don't know that it's all. That's why I didn't write all.
THE VIDEOGRAPHER: I'm going to go off the record to change tapes, sir. It's 5:35. One moment.
(Off the record.)
THE VIDEOGRAPHER: This is the beginning of Tape No. 8. It's 5:36 p.m.

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MR. ANDERTON: Mr. Farley, subject to my review of the documents that were produced today, the draft reports and such, at the moment I don't believe I have any further questions. I'm going to leave the record -- Pete -- Mr. Miller is going to make a responsive comment. So don't get up and leave just yet.
THE WITNESS: I'm here.
MR. ANDERTON: So I reserve the right to reconvene this session on behalf of Defendants in the event our review of those documents suggests further examination based on those documents as necessary.
THE WITNESS: Yes. I understand.
MR. MILLER: To the extent your review of documents you -- if you believe from that review that you need to come back then I would say that we restrict it obviously only to his documents.
But my position would be that I offered up a vast majority of those documents before lunch and certainly we could have gone over the rest of them during lunch.
I think you've had ample opportunity to review them. But we'll look at this more as we go forward and decide.

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MR. ANDERTON: Well, actually -- before I close the record -- I almost -- let's not mess this up. I don't have copies of those.
MR. MILLER: You do. It's on the thumb drive.
MR. ANDERTON: I need hard copies if I'm going to introduce them as exhibits. If you want to minimize the -- I'm going to mark them and introduce them.
MR. MILLER: All right. But you asked for the thumb drive and we gave them to you on the thumb drive.
MR. ANDERTON: I understand. I don't have --
MR. MILLER: I mean, there's not a requirement to give you multiple copies. You've got copies. And if --
MR. ANDERTON: Can I take that and get copies made, Pete?
MR. MILLER: Yes.
MR. ANDERTON: Okay.
MR. MILLER: Well, I've got questions before we close this.
MR. ANDERTON: Well, I don't have time. This --

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MR. MILLER: I've got five minutes of questions.
MR. ANDERTON: Pete --
MR. MILLER: You can sit here or not sit here. I've got five minutes of questions.
MR. ANDERTON: We're past 5:30. We've got a PTL that says we cut off at 5:30.
MR. MILLER: Well, I mean, I've got five minutes.
MR. ANDERTON: So it sounds -- no, Pete. I'm not missing my flight. I don't have --
MR. MILLER: You're not going to miss your flight. I'm going to ask four questions.
MR. ANDERTON: I don't have the ability to --
MR. MILLER: I'm going to ask these questions. So you do have the ability. Just pack up while I'm -- I'll be done before you get everything packed up. Okay? Allow me to ask these questions.
MR. ANDERTON: Okay.
MR. MILLER: Thank you.
Mr. Farley --
MR. ANDERTON: Wait. Before you do that, we're going to mark these documents. So if you

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want to -- I mean, she's got to mark these exhibits.
I suggest actually we just allow her to mark those. She'll take them. I'll get copies from her and you can print new copies.
MR. MILLER: I'll get copies from her as well. That's fine. I have no problem with that.
MR. ANDERTON: Okay.
MR. MILLER: But let's mark them after I get done with my time.
MR. ANDERTON: Well, you can mark those after we leave.
THE COURT REPORTER: I can.
MR. ANDERTON: Okay.
MR. MILLER: Perfect.

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CROSS EXAMINATION

BY MR. MILLER:

Q Mr. Farley, you were asked extensively about the EIR with the September 2007 FDA inspection. Do you recall that?
A Yes.
Q And you were asked several times about the corrections, voluntary corrections, that were put in place from the 15 observations that were made on the

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previous inspection, correct?
A Yes.
Q And because observation -- or correction. Because corrections have been proposed and implemented as noted by the FDA, that doesn't mean that they are successful; is that correct?
A That's correct.
Q Okay. And ultimately following regulatory investigations will determine if they were successful or not; is that correct?
A That's correct. And that's the point I was trying to make.
Q Thank you. And on your conclusions, sir, looking at that first paragraph of conclusions -- and I won't read them all. But that first sentence of the first conclusion, Based on the review of the documents listed in this report I conclude that Actavis had essentially no quality control over the products it produced and shipped.
Did I read that correctly, sir?
A Yes.
Q And you base that opinion on all the documents that you reviewed, correct?
A Yes.
MR. ANDERTON: Peter, are you leading --

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wait.
MR. MILLER: You can object.
MR. ANDERTON: I am objecting. You've got to give me a chance.
MR. MILLER: All right. I didn't hear the word objection. I'm sorry.
MR. ANDERTON: Objection. You're leading the witness.
BY MR. MILLER:
Q Was speculation required in any way in determining your opinions?
A My speculation?
Q Yes.
A No. It was based on opinions from my experience.
Q Fair enough. And that's true with all the opinions that you have in this report; is that correct, sir?
MR. ANDERTON: Objection. Again, are you -- is this cross-examination? Direct examination? What --
MR. MILLER: I didn't hear objection.
MR. ANDERTON: Objection, leading.
MR. MILLER: Thank you.
BY MR. MILLER:

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Q Did you have to speculate in any way on all the opinions in this report?
A I didn't speculate on anything. I used my opinion based on my best judgment and my years of experience and knowledge.
Q Did you feel you had a satisfactory amount of information to make the opinions that you've rendered in this report?
A Yes, I do.
Q Okay. Was anything said today that affected any of your opinions?
A No. While various other documents that I had not seen were mentioned they, I believe, would not affect my opinions.
Q Okay. And were all these opinions given to a reasonable degree of scientific certainty?
A Yes.
MR. MILLER: That's all the questions I have.
- - - - -
REDIRECT EXAMINATION
BY MR. ANDERTON:
Q Okay. I have a couple follow-up questions, Mr. Farley.
A I'm here.

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Q Is GMP compliance evaluation a science?
A It's not considered a science. It's a system like total quality management is a system. It's the FDA's equivalent of total quality management.
Q So when you were asked a moment ago whether they were rendered with a reasonable degree of scientific certainty, what did you mean when you said yes?
A I interpreted that as Peter Miller was asking me about my scientific knowledge, my work experience. That's how I interpreted that when I said yes. It's my scientific certainty.
Q Yeah, but in the area of GMP compliance it's not scientific knowledge. It's, as you said, specialized perhaps but not scientific.
A Well, chemists, physicists and some other scientists have what we call the scientific way of thinking, the logical way of thinking. And we're rather proud of it, in fact. And when I was asked if it's scientific or whatever deduction, I said yes, meaning my scientific way of thinking.
MR. ANDERTON: Thank you. I have no further questions. And again, I reserve the right to reconvene based on --
THE WITNESS: Yes.

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MR. ANDERTON: But we're going to mark --
THE VIDEOGRAPHER: Read and sign?
MR. MILLER: Yes.
MR. ANDERTON: We're going to mark the documents in this binder -- how many are there?
MR. MILLER: How many? Several. You want to go by tab? Each one of these is an individual file on that thumb drive. Like you're going to see these are several documents. But each one of those is going to be --
MR. ANDERTON: Okay.
MR. MILLER: -- a document on the thumb drive. We'll just go by tabs. We're going to group each one in tabs.
MR. ANDERTON: Okay. So you can mark the -- each tab in that white binder as an individual document. And those can be -- well, let's call it Defendants' Exhibit 100, just to be safe. And start with 100 and go up.
And then the draft reports is, what I'll call them -- I'm not sure they're actually drafts according to Mr. Farley. There are three. You can make those 45A, 45B and 45C.
THE COURT REPORTER: Okay.
MR. ANDERTON: Okay? And then if you

will -- we'll contact you to get copies.
THE COURT REPORTER: Okay.
MR. ANDERTON: Okay? Thank you very much.
THE VIDEOGRAPHER: All right. The deposition is concluded and it is 5:44 p.m.
(Defendants' Exhibit Nos. 45A, 45B, 45C, 100, 101, 102, 103, 104 and 105 were marked.)
(The proceedings were concluded at 5:44 p.m.)



ERRATA SHEET

I, the undersigned, JAMES J. FARLEY, do hereby certify that I have read the foregoing deposition and find it to be a true and accurate transcription of my testimony, with the following corrections, if any:

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JAMES J. FARLEY Date

ASG



CERTIFICATE

GEORGIA:
CHATHAM COUNTY:

I, Angela S. Garrett, Certified Shorthand Reporter for the State of Georgia, do hereby certify:

That the foregoing deposition was taken before me on the date and at the time and location stated on Page 1 of this transcript; that the witness was duly sworn to testify to the truth, the whole truth, and nothing but the truth; that the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed by computer-aided transcription; that the foregoing deposition, as typed, is a true, accurate, and complete record of the testimony of the witness and of all objections made at the time of the examination.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.



Witness my hand, I have hereunto affixed my official seal this 6th day of July, 2010, at Savannah, Chatham County, Georgia.

_____
Angela S. Garrett, CSR, RPR

D I S C L O S U R E

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_____ Date: July 6, 2010

Angela S. Garrett

RPR, CCR-B2407